Traffic-Related Air Pollution and Asthma in Economically Disadvantaged and High Traffic Density Neighborhoods in Los Angeles County, California

Final Report - APPENDICES
June 12, 2009

ARB Contract No. 04-323

Appendix A
Example Field Log Sheet – Site Description

Log Sheet and Protocol for Ogawa Sampling

I. SITE INFORMATION

Name of Field Monitor(s):	
Site ID#	
Shelter ID#:	

II. LAND USE: Please check one

	Commercial (Store, Restaurant, Mall)
	Office Building (Business, Lawyer, Doctor, Dentist)
	Residential (Houses, Apartments, Trailer Parks)
	Open Space (Parks, Undeveloped Land, Water bodies
	Government (Hospitals, Government Offices, Schools, Courthouses)
	Industrial (Factories, Power Plants, Waterhouses, Utility Plants, Land Fill)
	Parking Lots
	Transportation Centers (Bus Stations, Train Stations, Airport)
	Other

BRIEF SITE DESCRIPTION**:**

Take several (2-3) pictures to show the relative location and help us find the location at the next visit ("shelter view"). Please show the site information (first box above) in the first picture you take.

III. SAMPLING PROTOCOL

Step	Task	Status
1	Identify a site to mount the sampler/shelter. Mounting options include a fence, post, downspout from rain gutter, tree limb, etc.	Complete? (Please circle) YES
2	Briefly describe the location selected for mounting	
3	Is the location away from busy driveways, garages, parking lots and other obvious sources of vehicle exhaust?	YES
4	Get one shelter and secure the cover using cable ties. If necessary, use multiple cable ties to secure the shelter.	Complete? (Please circle) YES
5	Are the cable ties pulled **TIGHTLY** so that the samplers will stay in place for two weeks?	YES
6	Is the shelter completely flat to ensure that rain/water does not enter?	YES
7	Measure and record the height from the ground to the bottom of the shelter. **Aim for approximately 9ft or 108 inches.**	_____ft. _____in.
8	Warm up GPS for 5 minutes before taking the reading to make sure we get a good satellite signal.	Complete? (Please circle) YES
9	Is the GPS recording in DEGREES?	YES
10	Is the NORTH AMERICAN DATUM 83 (NAD 83) being used?	YES
11	Have one team member take a reading and record Lat, Long, and Accuracy	Longitude: _____ Latitude:_____ Accuracy _____
12	Have a second team member take a reading and record Lat, Long and Accuracy	Longitude: _____ Latitude:_____ Accuracy _____
13	Take a third reading, called a WAYPOINT	Longitude: _____ Latitude:_____ Accuracy _____
14	Take picture of a piece of paper with the Site ID # for this site.	Complete? (Please circle) YES
15	Take 4 –6 photos to show complete 360 degree angle view from the shelter (“land view”)	Complete? (Please circle) YES

Once you return to the office, please save your photos to CD-ROM and rename the picture files as "site ID_Land1", "site ID_Land2", etc. for land view in section III and "site ID_shelter1", "site ID_shelter2"for shelter view in section II (ie, for site ID=001, the first land view picture should be named "001_Land1")

IV. ADDITIONAL FIELD MONITORING NOTES:

Appendix B
Example Field Log Sheet – Installation and Collection Times, GPS Coordinates

Name(s) of person installing			
Date of installation	**9/16/2006**	**Day of week**	**Saturday**

Site ID	Time of installation	Height	Need pictures?	All pictures taken?	Same site?	Latitude (1)	Longitude (1)	Accuracy (1)	Latitude (2)	Longitude (2)	Accuracy (2)

Name(s) of person removing			
Date of removal	9/30/2006	**Day of the week**	Saturday

		Time window for removal								
Site ID	**Time installed**	**Earliest allowable time**	**Latest allowable time**	**Time monitor removed**	**Latitude (1)**	**Longitude (1)**	**Acc (1)**	**Latitude (2)**	**Longitude (2)**	**Acc (2)**

Appendix C
Final Report for Contract 05-311 and Contract 05-312, Spirometry Training and Grading of Spirometry Test Results in conjunction with Wave Two of the Los Angeles Family and Neighborhood Survey (L.A. FANS)

Spirometry Training and Grading of Spirometry Test Results in conjunction with Wave Two of the Los Angeles Family and Neighborhood Survey (L.A. FANS)

Final Report
April 29, 2009

Submitted by:
Dr. Kathleen Mortimer and Mr. Lucas Carlton

Background:

A large literature links outdoor air pollution exposure to adverse respiratory health effects in children and adults.[1-7] Ozone (O_3) and particulate matter less than 10 and 2.5 microns in aerodynamic diameter (PM_{10} and $PM_{2.5}$) are the pollutants that have been most consistently linked with adverse respiratory health, particularly in asthmatics. Children are likely to be particularly vulnerable to air pollution impacts due to the large volume of air inhaled each day and subsequent delivery of substantial pollutant doses to the respiratory tract; they also typically spend more time than adults exercising outdoors.[8] A growing literature links outdoor air pollution exposure to worse asthma morbidity in children.[3-10] Although the link between air pollution and exacerbation of existing illness is well-established, recent evidence has also pointed to the potential importance of air pollution exposure in the development of chronic disease.[4-5,7] Existing studies have reported associations between PM_{10}, O_3 and NO_2 and reductions in lung function, slowed lung growth, chronic cough and bronchitis.[11-23] Recently, focus has turned to potential adverse respiratory effects caused by exposure to specific motor vehicle exhaust components such as polycyclic aromatic hydrocarbons (PAHs) sorbed to particles from diesel engines and ultrafine particles (less than 0.1 microns in aerodynamic diameter), which can penetrate deep into the lung.[24-26] A series of recent studies (mostly in Europe) linked various measures of traffic exhaust exposure (community-level NO_2, home outdoor NO_2, residential and school proximity to traffic) to asthma prevalence, atopy, and wheezing.[27-31] In a recent school-based study, Kim et al.[32] reported associations between current asthma in Californian 3rd to 5th graders and measured concentrations of traffic-related pollutants (black carbon (BC), nitrogen oxides (NO_x) and nitrogen oxide (NO)). Although children are often noted as a particularly susceptible population, there is wide evidence that adults (especially asthmatics) are impacted by exposure to ambient air pollution, and recent work has also pointed towards traffic-related air pollutants in particular as an area of concern for adult health impacts.[33-48]

Although existing air monitoring networks provide a reasonable surrogate measure of long-term exposure to pollutants that are relatively homogeneously distributed within communities, this may not be the case for primary traffic-related pollutants – such as diesel exhaust particulate – which show strong spatial gradients.[7] There is currently a lack of neighborhood and individual level air pollution measurements for Californians that live in high traffic density areas and who may be more susceptible to adverse health impacts from air pollution exposure due to economic disadvantage. Although efforts have been and are being made to develop reliable models to assess exposures at a finer spatial scale, additional measurements in Los Angeles County communities with varying amounts of socioeconomic disadvantage and major air pollution sources would help inform and validate these models. Thus, Dr. Beate Ritz (UCLA) received funding from the California Air Resources Board (CARB) for a project titled "Traffic-Related Air Pollution and Asthma in Economically Disadvantaged and High Traffic Density Neighborhoods in Los Angeles, California". The objectives of this project are: (1) to conduct NO_x and NO_2 monitoring at 200 locations within LA County neighborhoods with varying levels of economic disadvantage and varying exposures to air pollution originating from vehicular sources; (2) to use these monitoring data to help inform land use-based regression (LUR) models developed to predict traffic pollutant – i.e., NO_x, NO and NO_2 – exposures; (3) to use geostatistical models to estimate regional background concentrations of O_3 and $PM_{2.5}$; (4) to evaluate associations between exposure to NO_x, NO and NO_2 (as estimated by the developed

LUR models) and measures of lung function and asthma prevalence, exacerbation and possibly incidence in children ages 0-17 years in conjunction with the Los Angeles Family and Neighborhood Survey (L.A. FANS) study;[49] and (5) to evaluate whether concentrations of the more regionally distributed background pollutants (O_3 and $PM_{2.5}$) confound or modify the effects of exposure to the more heterogeneously distributed traffic-related pollutants (NO_x, NO and NO_2) on lung function and asthma. Because the L.A. FANS study is already established, includes follow-up of a cohort, by design focuses on disadvantaged neighborhoods and children, performs at-home interviews, and collects extensive data on neighborhood characteristics, including access to health care and neighborhood perception, it provides a unique opportunity for evaluating associations between air pollution and asthma. This report summarizes the work of Lucas Carlton to train L.A. FANS interviewers in collection of lung function measurements in conjunction with the UCLA project. It also summarizes methods used to review and grade collected spirometry data to provide feedback to field interviewers on where improvements were needed in data collection. The grading will also be used to determine which spirometry maneuvers are valid for use in statistical analyses.

The Los Angeles Family and Neighborhood Survey (L.A.FANS) is a longitudinal study of families in Los Angeles County and of the neighborhoods in which they live. The study is specifically designed to answer key research and policy questions in several areas, with a focus on understanding neighborhood, family, and peer effects on children's development and well-being. The first wave of data collection (L.A.FANS-1) was a field survey of 3,090 households conducted from April 2000 to January 2002. L.A.FANS-2 is a continuation of this study and is funded by grants from NICHD, NIA and NIEHS. It is a collaboration of three institutions: RAND, UCLA, and Research Triangle Institute (RTI). The protocol for L.A.FANS-2 is to re-interview all respondents from L.A.FANS-1 and to add a new sample of residents who have moved into each neighborhood between the two waves. L.A.FANS-2 was also expanded to collect objective physiological health measures or "biomarkers" from approximately 1,600 respondents. During the planning process for L.A.FANS-2, it was determined that the proposed approach for lung function testing (which is one of the physiologic measures being collected) in children could be greatly improved by using portable spirometers instead of peak flow meters as originally proposed.

Although the use of peak flow measurements to assess lung function has been advocated by the National Asthma Education and Prevention Program, the value of such measurements is limited because PEFR is effort dependent and reflects only flows of the large airways.[50] Furthermore, existing studies indicate peak flow meter recordings are not highly reproducible and appear to be no better at predicting asthma exacerbations than monitoring asthma symptoms alone.[50-54] Specifically, PEFR measures appear to be no better at predicting asthma than standard questions regarding doctor diagnoses and symptoms asked on questionnaires. Portable spirometers offer an advantage over peak flow meters because these instruments can measure a wide range of pulmonary function parameters (forced vital capacity (FVC), forced expiratory volume after 1 second (FEV_1), forced expiratory mean flow between 25% and 75% of FVC (FEF_{25-75}), and forced expiratory mean flow at 75% of FVC (FEF_{75})) which reflect conditions in both small and large airways and are more sensitive to changes in functional status in asthma.[50,55] Most studies of air pollution and asthma reported statistically significant but clinically small effects on PEFR and FEV_1.[12] Therefore, more recent work – such as the Fresno Asthmatic Children's Environment Study (FACES) – focused on measures such as FEF_{25-75} and FEF_{75} that may be more sensitive indicators of air pollution health effects. The University of Southern

California's (USC's) Children's Health Study (CHS) focuses on asthma and lung development in 4th through 10th graders living in 12 Southern Californian communities and has reported larger percentage effects of air pollution on lung growth based on FEF_{25-75} and FEF_{75} measures compared to PEFR and FEV_1.[56] Finally, use of spirometry allows for comparisons to other studies focused on childhood asthma, such as the CHS, FACES and the CDC-funded Oakland Kicks Asthma (OKA) project. Thus, the Principal Investigators for L.A. FANS (Dr. Anne Pebley (UCLA) and Dr. Narayan Sastry (RAND/University of Michigan)) applied for and received additional NIEHS funding to use portable spirometers to measure lung function instead of peak flow meters.

The EasyOne Frontline Spirometer from ndd Medical Technologies was selected for the LA FANS Wave-2 field work (http://www.ndd.ch/English/Products/EasyOne_fs.html). The key features of this instrument that make it well suited for the study are: (1) it is small, portable, and requires minimal power (approximately 400 measurements can be completed with two AA alkaline batteries), (2) has the ability to record and store approximately 700 sessions of spirometric data in memory including full flow-volume curves, (3) includes quality control software and prompts to obtain acceptable and repeatable efforts, (4) has time and date stamping of all records, (5) allows easy transfer of specific flows and volumes to a personal computer database, (6) can be re-used to test multiple subjects with minimal cleaning, (6) allows easy calibration, and (7) complies with American Thoracic Society (ATS) criteria for spirometer performance. A recent evaluation by the FACES study team indicated this spirometer accurately and reliably measures pulmonary function in children, relative to a "gold-standard" laboratory-style instrument (see Mortimer, et. al. 2003 for details).

Based on discussions and collaboration with members of the Fresno Asthmatic Children's Environment Study (FACES) and input received from CARB internal and external reviewers during the UCLA grant proposal review process, additional training was recommended for L.A. FANS field interviewers to help increase the quality of lung function data, especially data collected for children (some of which will be as young as 5 years old). This report summarizes the work of Dr. Kathleen Mortimer and Mr. Lucas Carlton to train L.A. FANS interviewers in collection of lung function measurements in conjunction with the UCLA project. In addition, it was also recommended that all collected spirometry curves be graded on an on-going basis for quality review and to provide feedback to field interviews on where improvements were needed during data collection. Dr. Mortimer and Mr. Carlton have extensive experience in using the EasyOne spirometer to assess lung function and in reviewing spirometry curves, especially in asthmatic children where these manuevers can be most difficult, based on their work on the FACES project at UC Berkeley.

Project Objectives:

The objectives of this subcontract were to provide training to the L.A. FANS-2 field interviewers on how to successfully administer spirometry tests using the EasyOne portable spirometer and to review and grade spirometry test results from subjects interviewed in the L.A. FANS-2 study. Although training and subsequent data collection includes both adults and children, parts of the training were specifically tailored to performing tests with children, since that is the main focus of the CARB-funded UCLA study of air pollution impacts.

Description of training:

The training sessions for field supervisors and field interviewers were held on October 11, 2005 (at the RAND Corporation), and on August 14-15, 2006 and April 16, 2007 (at the Marriott Hotel, Marina Del Rey). All field interviewers were required to attend at least one training session. The April 16, 2007 training included new field interviewers who were being trained for the first time, as well as existing field interviewers who were having trouble achieving good spirometry tests in their interviews. At the first training (October 11, 2005), each of the 8 field interviewers attended a 2-hour training session led by two technical representatives from ndd Technologies, the makers of the EasyOne spirometers. These sessions were focused on the instruments themselves, and the technicians went over how to turn the machine on, how to enter subject-specific characteristics, how to place the spirette properly in the instrument prior to the maneuver and how to perform the maneuver. The interviewers then practiced performing the maneuvers themselves. In the afternoon, these 8 field interviewers attended a 4-hour spirometry training led by Dr. Kathleen Mortimer and Lucas Carlton from the U.C. Berkeley FACES study. During all sessions, Dr. Michelle Wilhelm and Jo Kay Ghosh, both from UCLA, assisted Dr. Mortimer and Mr. Carlton with the training by helping the interviewers with the device set up and acting as "participants.". At the subsequent training sessions, there were two training session each day. Each session lasted approximately 4 hours, with one group of interviewers receiving training in the morning, and a different group receiving the training in the afternoon. The training sessions in October 2005 and August 2006 were led by Dr. Mortimer and Mr. Carlton, while the April 2007 training session was led only by Dr. Mortimer.

In the first 2 hours of the training, Dr. Mortimer and Mr. Carlton began the training session by reviewing the general purpose of collecting spirometry data, emphasizing how this can provide data on a person's lung function, and how this relates to asthma outcomes (see Appendix 1 for the materials provided to the interviewers in conjunction with this part of the training). They explained the different lung function measurements that can be obtained from the spirometer (FEV1, FVC, etc.) (Table 1) and also went over the volume versus time and flow versus volume curves. They then demonstrated a typical spirometry session, including preparing the spirometer for data collection, explaining the procedure to the participant, having the participant conduct several trials until he/she achieved three "successes", and coaching the participant to give the best effort during each trial. The "participant" for this part of the training was one of the study investigators who knew how to correctly perform a spirometry test. Thus, this gave the interviewers a "first look" at the correct way to collect such data. Afterward, they asked each field interviewer to set up their own spirometer for a test, including turning on the machine, entering a subject's name, date of birth, height and weight, and placing the spirette properly in the instrument prior to the maneuver (see Appendices 2-4 for materials provided in conjunction with this part of the training). Since there was some confusion among a few of the interviewers in terms of how to enter data using the keypad on the EasyOne, they reviewed each interviewer's spirometer with them to make sure each one was set up correctly, and that the interviewers understood how to enter both numbers and letters in each field.

In the second part of the training session, in addition to demonstrating a successful spirometry trial, they demonstrated common mistakes and showed the field interviewers what these mistakes looked like in practice, and on the spirometry graph displayed on the EasyOne's screen (see Appendix 5 for example curves). Specifically, they demonstrated what these maneuvers look like when mistakes occur and also showed the resulting curves and pointed out the problem areas. They also discussed the importance of obtaining acceptable and reproducible curves. Per ATS standards and the L.A. FANS study protocol, the goal is to obtain 3 acceptable

and 2 reproducible curves within a maximum of 8 tries from each subject. Common mistakes include not blowing hard enough or fast enough, sucking in air initially before blowing, blowing in multiple blasts, hesitating before blowing, and not blowing long enough. They provided strategies for improving the participants' technique. For example, one common mistake is that the participants bend over while blowing. The trainers recommended several strategies to remind the participant to stand up straight and only bend their legs while blowing into the spirometer.

Table 1. Basic spirometry measures and definitions[57]

Spirometry measurement	Abbreviation	Description
Forced Vital Capacity	FVC	This is the total amount of air forcibly blown out after full inspiration, measured in liters.
Forced Expiratory Volume in 1 Second	FEV1	This is the amount of air forcibly blown out in one second, measured in liters. Along with FVC it is considered one of the primary indicators of lung function.
Peak Expiratory Flow	PEF	This is the speed of the air moving out of the lungs at the beginning of the expiration, measured in liters per second.
Forced Expiratory Time	FET	This measures the length of the expiration in seconds.
Forced Expiratory Flow at 25% of FVC	FEF_{25}	This is the flow of air measured at the time when 25% of the entire FVC has been expelled.
Forced Expiratory Flow at 75% of FVC	FEF_{75}	This is the flow of air measured at the time when 75% of the entire FVC has been expelled.
Forced Expiratory Flow between 25% and 75% of FVC *	FEF_{25-75}	This is average flow of air measured during the interval between the time when 25% and 75% of the entire FVC has been expelled.

* FEF_{25-75} is also called Maximum Midexpiratory Flow (MMEF)

They laid out the specific instructions that need to be given to the subjects and the physical steps that should be taken to obtain a successful test. They encouraged the interviewers to write these steps down and even read them while they are practicing maneuvers so that they become second-nature (see Appendix 4 for a short "cheat-sheet" they gave to the interviewers to help them memorize the instructions given to subjects). They also encouraged the interviewers to be very energetic while testing children and demonstrate the maneuver so that the children understand what is required. One suggestion was to do the maneuver alongside the children at the same time as a guide, if necessary. Another suggestion was not to have other children in the same room if a child appears embarrassed about doing the maneuver. Although the interviewers were encouraged to speak loudly, including "Blast out", they were instructed to speak more quietly to children who might be frightened or feel they were being yelled at for poor performance. The specific steps were covered numerous times by having the field interviewers practice among themselves and with the trainers' supervision.

To give the interviewers another perspective in how to coach the spirometry maneuver, the trainers asked an interviewer to help demonstrate how to conduct a session. This was used as an example of incorporating various personal elements into the explanation of the test to the participant, coaching the participant, and correcting the participant if needed. During this example, the interviewers saw first-hand the key elements of a successful spirometry session, and how best to interact with a participant. In particular, it was important for interviewers to see the complete explanation of the procedure, the exact order of setting up the spirometer and explaining the steps to the participant, and how to encourage the participant to give their best effort during the spirometry session. Interviewers were encouraged to use certain key phrases while the participant is blowing (e.g. "Blast out", "Keep blowing", "you're doing good", "you're almost there"), and also the use of analogy in describing how the participant should take a deep breath and blow into the spirette (e.g. "take a deep breath as if you were about to dive

underwater", "blow out like you're trying to force all the air out of your lungs"). Using an interviewer to demonstrate the procedure was effective in allowing interviewers to see the procedure from start to finish, give them ideas on what's effective and what's less effective, and allow them to ask questions about specific elements of the coaching and participant interaction.

The last part of the training involved practicing maneuvers on volunteers. During the first session (October 2005), children volunteers ages 5-15 years were the practice participants. At the subsequent sessions, interviewers practiced the maneuver on one another. The trainers observed the interviewers during these practice sessions and made suggestions about how to better coach the participants.

Almost all field interviewers were able to obtain successful maneuvers by the end of the practice sessions. The field supervisors noted any interviewers who were not able to obtain successful maneuvers during the practice session, so that follow-up could be done. All field interviewers had a rolling briefcase which contained all of their required interviewing materials including the spirometer and to supplement the training, they were asked to take the spirometers home to practice on their own children and/or children in their neighborhood or friends' children. Each interviewer was also given a test by their field supervisor at the end of their total two-week training (which included many other elements besides lung function testing).

Description of grading of spirometry test results:

It is important to note that the acceptability criteria coded into the EasyOne software may not be applicable to all participants or all efforts. Specifically, the EasyOne software does not detect all faulty curves that can be identified only through visual inspection of the hard copies. Examples include tests which did not start at the origin (early starts) and tests with negative flow toward the end of the test (subject took a breath before the end of the test). Conversely, the EasyOne software may also reject tests that are actually acceptable upon visual inspection. For example, the EasyOne may indicate "early end of test", meaning that the subject did not expel air long enough. Upon review of the data from this subject, however, it may be noted that the curves were actually acceptable if obtained from a young child. Children will not have the lung capacity to blow out for three seconds, which is the standard programmed into the EasyOne software. This pointed to the importance of reviewing the spirometry curves of subjects to confirm their acceptability or unacceptability.

We set up a standard protocol to share and transfer data in a secure manner across the several institutions participating in this project. After each set of field interviews was completed, the interviewers sent their EasyOne spirometers to RTI for downloading of spirometry data into the EasyWare MS Access database. The database was then uploaded onto a secure FTP (sFTP) server at UC Berkeley. Only senior project staff requiring access to these data had access to the sFTP server (each user was given a unique user name and password). To maximize time efficiency and to allow for periodic monitoring of data quality, Mr. Carlton graded each batch of data as received from RTI (approximately once a month to every two months).

In addition, an electronic form was added to the database, so that all the grading and comments could be recorded directly into the database. The grading was done by looking at the shape of each curve, and some of the diagnostic criteria provided from the EasyOne spirometers, including the key spirometry measures presented in Table 1. Once the grading was complete for a batch, the data were summarized and results provided to the RAND project manager. The RAND project manager then provided these summaries to the field interviews. Figure 1 provides an example of grading summaries provided to RAND field interviewers. The percent of

curves that were acceptable and reproducible (determined as explained below) were summarized by age group and by technician identification number to help translate findings effectively to field interviewers. Field interviewers were re-trained by head interviewers as needed based on these findings.

The grading of the spirometry curves consisted of two parts: determining acceptability for each curve, and determining reproducibility in each subject. Acceptability means that the maneuver was completed correctly, for example, that the participant inhaled deeply, and exhaled fast enough and hard enough to get a good measure of lung function. Reproducibility means that the acceptable curves from the same person are similar enough (according to defined criteria) to be useful in determining the person's lung function.[57]

To determine acceptability, all grading of spirometry curves was done based on the following criteria:[57]

(1) The Back Extrapolated Volume must be ≤5% or 150mL, whichever is greater;
(2) Time to Peak Flow must be ≤120 milliseconds;
(3) No abrupt end to test;
(4) FET must be ≥ 2 seconds;
(5) Time/Volume curve must begin at origin (to ensure proper start of test);
(6) Curve must show that subject exhaled using only one continuous blast of air; and
(7) Curve must show no leaks or negative flow throughout test (i.e. no inhalation).

For each curve that was graded as "not acceptable", Mr. Carlton recorded a brief reason why the curve was rejected, such as "need to blow longer", "blow harder and faster", "don't hesitate", "late to peak flow", "bad effort", and "negative flow". These comments were used to help determine which aspects of spirometry coaching needed to be emphasized in on-going feedback to the interviewers and in subsequent the field interviewer training sessions.

After the curves were graded for acceptability, reproducibility was assessed in the acceptable curves. At minimum, a subject needed to have two acceptable curves in order to determine whether or not the curves were reproducible. We used the American Thoracic Society (ATS) guidelines, which specify that at least one FVC reading must be within 0.20 L of the largest FVC measure, and that at least one FEV1 reading must be within 0.20 L of the largest FEV1 measure for the same person. The ATS criteria are the most commonly used criteria for assessing reproducibility of spirometry curves.[57]

Overall, we graded spirometry curves for over 3,000 participants, including both children and adults. The large majority of these subjects (over 75%) were able to achieve 2 or more acceptable spirometry curves, and over 78% of these met the ATS criteria for reproducibility. Of subjects with 2 acceptable curves, 69% had curves that were reproducible. Of subjects with 3 acceptable curves, 83% had curves that were reproducible. Figures 2 and 3 provide final summaries of acceptability and reproducibility by age for L.A. FANS-2 child and adults respondents. Children <8 years of age were the least likely to be able to achieve 2 or more acceptable curves and ability to achieve 2 or more acceptable curves increased with age, reaching 80% in adults. Adults were most likely to achieve reproducible curves (over 63% were reproducible), and results were similar among teenagers (59%) and preteens (56%). However, children <8 years of age were far less likely to achieve reproducible curves (42%), partly due to many of the children being unable to obtain a minimum of 2 acceptable curves.

Summary and recommendations:
Overall, the field interviewers received 6 hours of spirometry training. At the end of the training day many expressed that they felt more training and practice maneuvers, especially with children, would be helpful. In future trainings, practice maneuvers spread over a few days may be ideal. The interviewers did take the spirometers home with them to practice on their own families and friends. The field interviewers were receptive to the material and efforts to improve their technique. They expressed that it gave them more confidence with the instruments. The L.A. FANS study team was also very appreciative of the training sessions and felt these sessions were essential for obtaining high quality lung function data.

After reviewing the data from the first several months of field interviews, the trainers found that the age groups having the most trouble achieving acceptable and reproducible spirometry curves were the pre-teens and teenagers. In the subsequent training sessions, they gave specific advice on how best to handle these age groups. They asked some of the more experienced interviewers and field supervisors to give their advice, which included reassuring that nobody (e.g. none of their peers) is watching, and reminding them that the sooner they get 3 acceptable curves, the sooner they will be finished. Additionally, some interviewers seemed to have more trouble with the spirometry than others. The trainers recommended that these interviewers pair up with an interviewer who had had more success with spirometry and/or that these interviewers be retrained.

Overall, the ratings based on the EasyOne pre-programmed software were in agreement with the technician ratings 96.2% percent of the time. However, using the technician grading, we were able to detect 55 additional acceptable spirometry curves (0.6%) that were rejected by the EasyOne software, and also reject 303 curves (3.2%) where problems occurred during the spirometry test (based on both adult and child curves). In regards to providing on-going feedback to field interviewers based on grading results, one recommendation for improvement would be to provide the review results on a more timely basis. Due to the logistics of the L.A. FANS study, data from each interviewer's spirometer was downloaded relatively infrequently and thus there was a lag of two to three months between data collection for some subjects and feedback. More frequent data downloading would allow field interviews to learn about and rectify mistakes more quickly.

Figure 1: Example of Periodic Summary of Spirometry Grading Results to Provide Feedback to L.A. FANS-2 Interviewers

Acceptability by Age

Age Group	Reviewer Accept			
	No acceptable curves	1 acceptable curve	2-3 acceptable curves	Total
<8 children	5	5	8	18
	27.78	27.78	44.44	
8-<12 preteen	0	1	23	24
	0	4.17	95.83	
12-<18 teens	4	1	27	32
	12.5	3.13	84.38	
18+ adults	7	7	95	109
	6.42	6.42	87.15	
Total	16	14	153	183

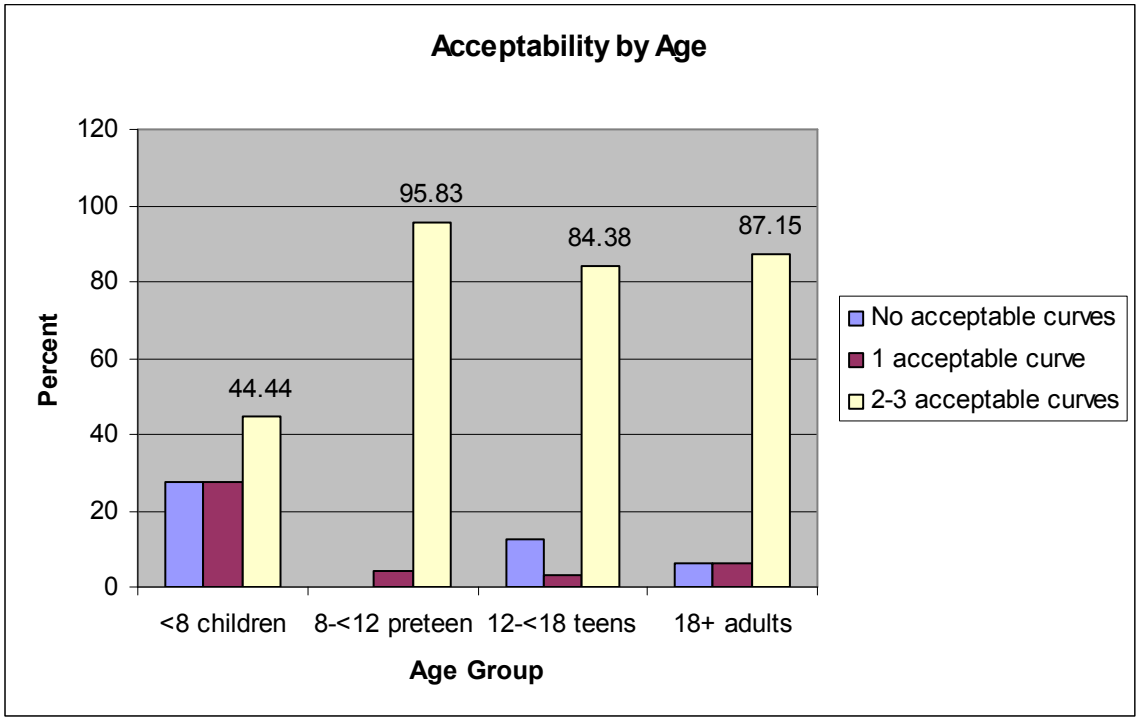


Figure 1 (continued): Reproducibility by Age

Age Group	Reproducibility, using ATS criteria, based on Reviewer grading			
	NA, <2 acceptable curves	Curves NOT reproducible	Curves ARE reproducible	Total
<8 children	10	1	7	18
	55.56	5.56	38.89	
8-<12 preteen	1	6	17	24
	4.17	25	70.83	
12-<18 teens	5	8	19	32
	15.63	25	59.38	
18+ adults	14	13	82	109
	12.84	11.93	75.23	
Total	30	28	125	183

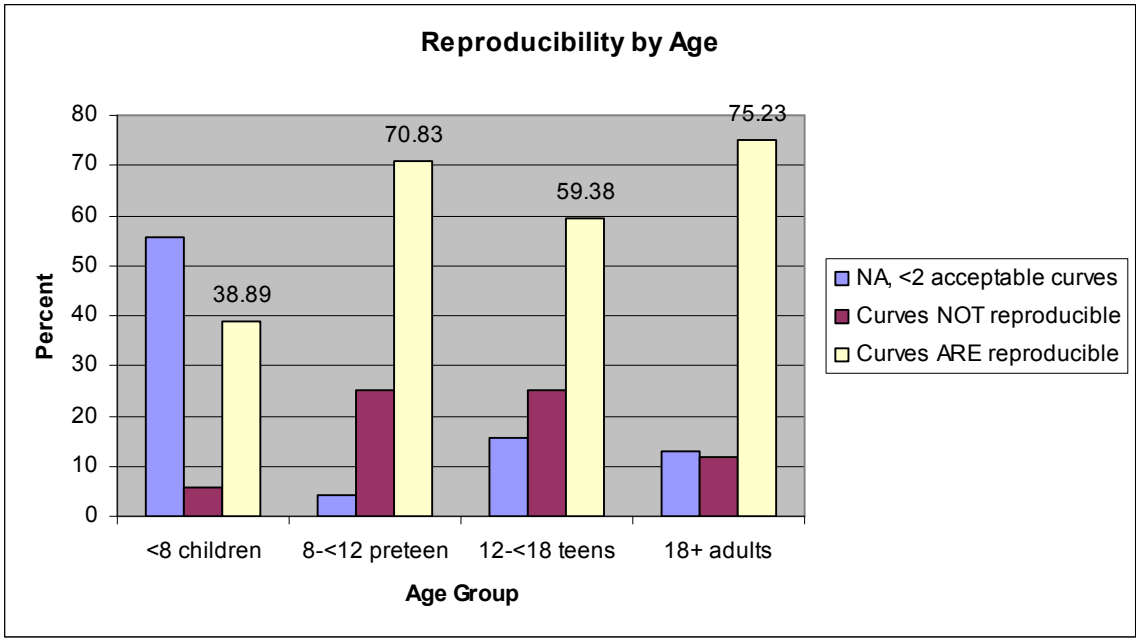


Figure 1 (continued): Acceptability and Reproducibility by Field Interviewer
Note: reproducibility is based on ATS criteria and reviewer grading

Acceptability by Field Interviewer:

	No acceptable curves	1 acceptable curve	2 acceptable curves	3 acceptable curves	TOTAL	No acceptable curves %	1 acceptable curve %	2-3 acceptable curves %
JHAR1	0	1	0	1	2	**0.0%**	**50.0%**	**50.0%**
549014	10	5	15	18	48	**20.8%**	**10.4%**	**68.8%**
NkAS1	2	0	3	5	10	**20.0%**	**0.0%**	**80.0%**
TRUHL1	0	1	3	1	5	**0.0%**	**20.0%**	**80.0%**
664243	1	1	2	8	12	**8.3%**	**8.3%**	**83.3%**
LAFMLOC1ON	2	2	3	23	30	**6.7%**	**6.7%**	**86.7%**
LAFESPY1	0	2	11	10	23	**0.0%**	**8.7%**	**91.3%**
MRAV1	0	2	10	26	38	**0.0%**	**5.3%**	**94.7%**
IBEL1	0	0	0	9	9	**0.0%**	**0.0%**	**100.0%**
LAFMLOC1	0	0	1	4	5	**0.0%**	**0.0%**	**100.0%**
Total	15	14	48	105	182	**8.2%**	**7.7%**	**84.1%**

Reproducibility by Field Interviewer:

	NA, <2 acceptable curves	Curves NOT reproducible	Curves ARE reproducible	TOTAL	**NA, <2 acceptable curves %**	**Curves NOT reproducible %**	**Curves ARE reproducible %**	TOTAL w/ 2+ acceptable	**% reproducible out of acceptable**
TRUHL1	1	2	2	5	**20.0%**	**40.0%**	**40.0%**	4	50.0%
JHAR1	1	0	1	2	**50.0%**	**0.0%**	**50.0%**	1	100.0%
549014	15	7	26	48	**31.3%**	**14.6%**	**54.2%**	33	78.8%
664243	2	2	8	12	**16.7%**	**16.7%**	**66.7%**	10	80.0%
LAFESPY1	2	5	16	23	**8.7%**	**21.7%**	**69.6%**	21	76.2%
NkAS1	2	1	7	10	**20.0%**	**10.0%**	**70.0%**	8	87.5%
MRAV1	2	8	28	38	**5.3%**	**21.1%**	**73.7%**	36	77.8%
LAFMLOC1ON	4	3	23	30	**13.3%**	**10.0%**	**76.7%**	26	88.5%
IBEL1	0	0	9	9	**0.0%**	**0.0%**	**100.0%**	9	100.0%
LAFMLOC1	0	0	5	5	**0.0%**	**0.0%**	**100.0%**	5	100.0%
Total	29	28	125	182	**15.9%**	**15.4%**	**68.7%**	153	**81.7%**

Figure 2. Final Acceptability by Age for L.A.FANS-2 Child and Adult Respondents

Age Group	Reviewer Accept			
	No acceptable curves	1 acceptable curve	2-3 acceptable curves	Total
<8 children	48	24	69	141
	34.04	17.02	48.94	
8-<12 preteen	57	39	258	354
	16.1	11.02	72.88	
12-<18 teens	75	55	442	572
	13.11	9.62	77.27	
18+ adults	193	190	1528	1911
	10.1	9.94	79.96	
Total	373	308	2297	2978

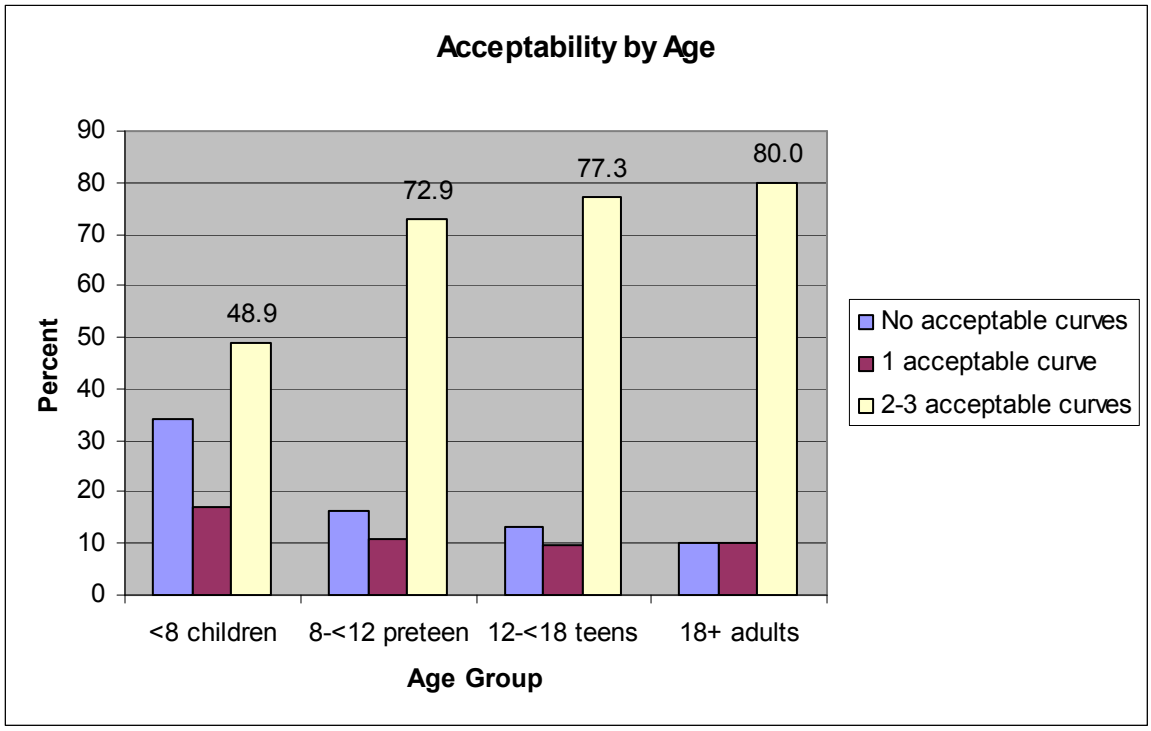
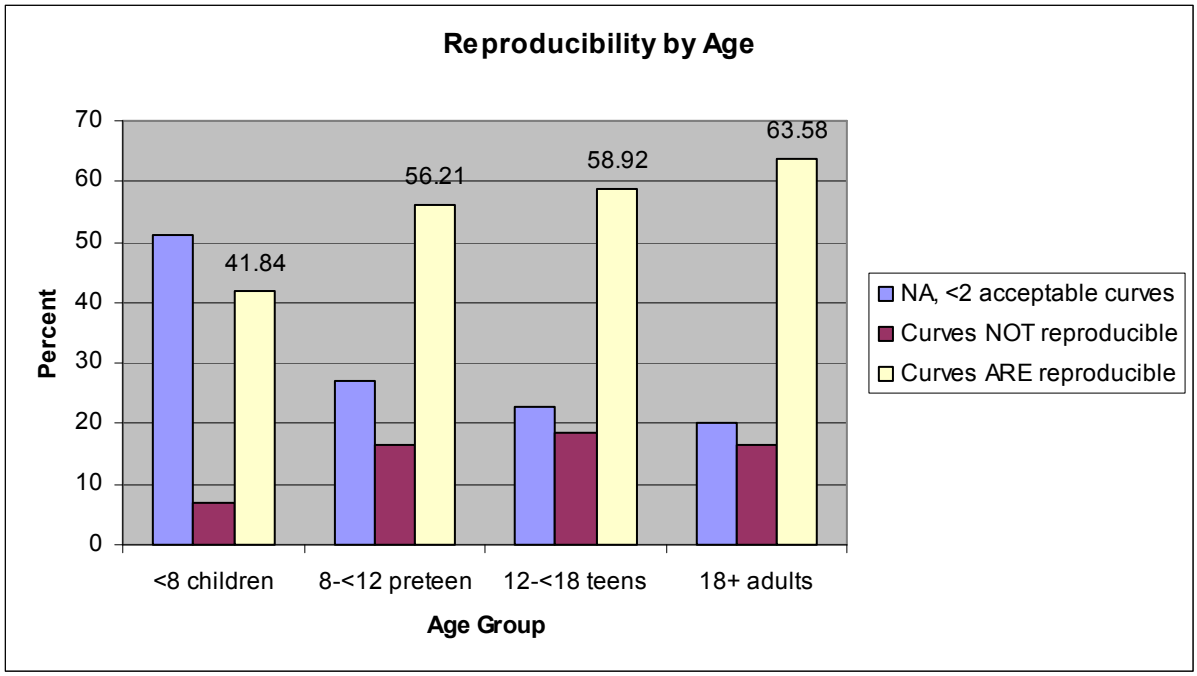


Figure 3. Final Reproducibility by Age for L.A.FANS-2 Child and Adult Respondents

Age Group	Reproducibility, using ATS criteria, based on Reviewer grading			
	NA, <2 acceptable curves	Curves NOT reproducible	Curves ARE reproducible	Total
<8 children	72	10	59	141
	51.06	7.09	41.84	
8-<12 preteen	96	59	199	354
	27.12	16.67	56.21	
12-<18 teens	130	105	337	572
	22.73	18.36	58.92	
18+ adults	383	313	1215	1911
	20.04	16.38	63.58	
Total	681	487	1810	2978



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List of Appendices:

1. **Spirometry overview**
2. **Spirometry instructions (detailed)**
3. **EasyOne instructions**
4. **LA FANS step-by-step instructions (brief)**
5. **Sample curves for training**

Appendix 1
L.A. FANS Spirometry Overview

SPIROMETRY

I. Introduction

The principle test of lung function is known as “spirometry” or the “forced vital capacity maneuver.” The basic principal behind the test is to have a participant fill his/her lungs with as much air as s/he can and then rapidly and forcefully exhale the air until s/he feels that no more air is left in his/her lungs. The spirometer records and saves information about volume, flow rate, and time. From this information a number of measurements can be made about the mechanical function of the person’s lung.

A high level of participant cooperation is required to obtain reliable results from this test. Failure to obtain a maximum effort with each test and/or lack of attention to other details that affect the test will lead to results that are not accurate or reproducible.

II. Measurements That Will be Made

A. FEV_1 - Forced Expiratory Volume in the first second:

measures the amount of air that the participant can exhale in the first second of forced exhalation.

1. This measurement is affected adversely if the participant starts the maneuver too slowly or does not blow as hard as s/he can right from the start.

B. FVC - Forced Vital Capacity:

measures the total amount of air that a participant can exhale after taking a full inspiration and then forcibly emptying the lung until no more air is left.

1. This measurement is affected adversely if the participant does not empty his/her lungs as completely as possible or if the participant does not blow out as forcefully as s/he can; paradoxically, the slower the participant blows, the larger the result will be (this is not what is desirable).

C. FEV_1 / FVC:

FEV_1 expressed as a percentage of FVC.

1. This is a clinically useful index of airflow limitation for an individual, particularly if they have abnormally high or low FVC.

D. $FEF_{25-75\%}$- Forced Expiratory Flow between 25 and 75%

the average flow of the exhale over the middle half (25% volume to 75% volume) of the FVC.

1. This is a more sensitive measure of small airway function than FEV1.

E. PEF - Peak Expiratory Flow Rate (also called PEFR):

the highest airflow rate obtained during the test.

1. It is the top of the curve in the Flow-Volume Curve and is measured in volume/time (L/min, L/sec).
2. PEF is a direct measure of large airway function.

EasyOne™ FACES 1.5.4
(c) zAB 2000
EasyWare 1.5.0.2
SN 40614

Patient Information

Name	
ID	
Age	
Height	
Weight	
Gender	
Ethnic	
Smoker	
Asthma	

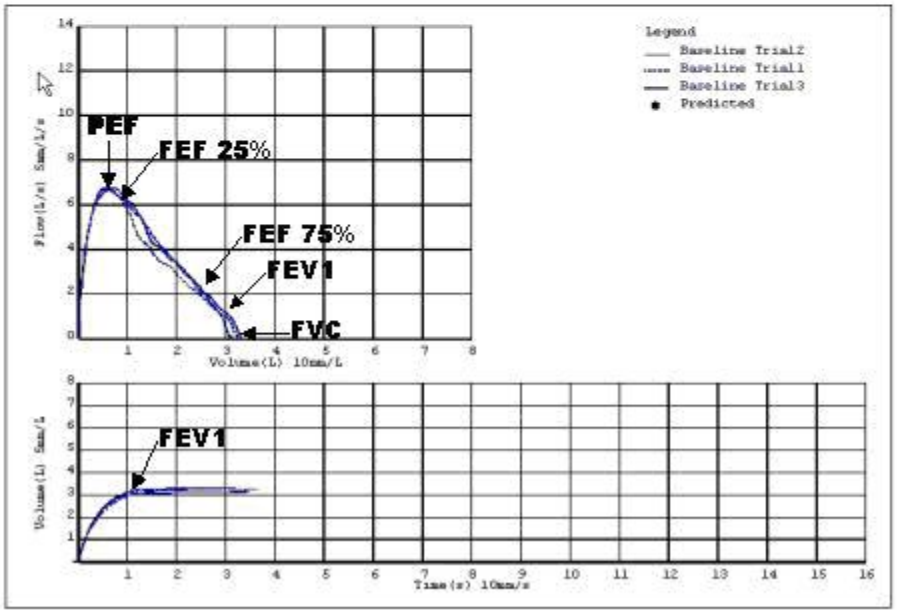
Test Information

Test Date	06/16/05
Test Time	07:55am
Post Time	--:--
Test Mode	DIAGNOSTIC
Predicted Ref	
Value Select	BEST VALUE
Tech ID	
Automated QC	ON
BTPS (IN/EX)	-.--/ 1.04

Test Results

Parameter	Baseline Best	Trial2	Trial1	Trial3	Pred	%Pred
FVC (L)	**3.30**	3.30	3.26	3.15	-.--	-.--
FEV1 (L)	**3.11**	3.11	2.98	3.00	-.--	-.--
FEV1/FVC	**0.94**	0.94	0.91	0.95	-.--	-.--
PEF (L/s)	**6.76**	6.76	6.67	6.74	-.--	-.--
FEF25-75 (L/s)	**3.75**	3.75	3.32	4.03	-.--	-.--
FEF75 (L/s)	**2.30**	2.30	2.02	2.47	-.--	-.--
BEV (L)	**0.08**	0.08	0.06	0.07	-.--	-.--
PEFT (s)	**0.09**	0.09	0.09	0.11	-.--	-.--
EOTV (L)	**0.00**	0.00	0.01	0.03	-.--	-.--
FET (s)	**3.19**	3.19	3.67	3.50	-.--	-.--

Baseline FEV1 Var = 0.12L 3.7%; FVC Var = 0.04L 1.4%; Session Quality A;
Interpretation No Interpretation possible; needed predicted value(s) can't be computed.



III. Testing/Coaching The Participant

A. Successful spirometry maneuvers don't happen by accident. Your ability to successfully coach the participant the first time around can lead to good compliance and performance on future spirometry tests. Take the time to learn successful coaching techniques and don't worry about looking silly!

B. Start by giving a simple, but full explanation to the participant of what the forced expiratory maneuver involves, as follows:

1. **"Please sit comfortably with both feet on the floor and, whenever you are ready, take as deep a breath as you can until it feels like you cannot get any more air into your lungs. Place your mouth around the mouthpiece with your lips tightly sealed, and then breathe out as hard, as fast and as long as you can. I want you to make the air "BLAST" out of your lungs. Keep breathing out until I tell you to stop."**

    a. Observe the participant carefully during the expiration to make sure that he/she has fully understood the instructions and is performing the forced expiration adequately.

    b. Encourage the participant to keep pushing air out of the lungs throughout the entire forced expiration; for example, tell the participant to "keep going, keep blowing…"

C. Continue by having the participant perform a second attempt, judging, through examination of the curves, whether the participant is performing the expiration correctly. Additional instruction may be needed, and this can only be judged by observing the participant and the curves produced. Once the person fully understands what is expected, the curves should all provide very similar measurements of FEV_1 and FVC, meaning that he/she should be able to expel most of the air (FVC) in the first second of the effort. Additional instructions which may be needed include the following:

1. **“Fill your lungs fully, then stop a moment, bring the spirette up to your mouth and breathe out as fast as you can.”**

2. **“Keep the spirette away from the mouth while you are breathing in.”**

2. **“Put the spirette between your teeth and seal your mouth around the mouthpiece, not allowing any air to leak out the sides.”**

3. **“Blow out as if you are saying the word ‘haaa’.”**

4. **“Try to keep going until I tell you to stop, even though it may feel like you are out of air.”**

5. **A demonstration by the tester of what the maneuver involves may be useful, using a spirette held in the hand.**

IV. Determining Acceptability of the Tracings[1]:

A. Determining a satisfactory end of the test:

1. An obvious plateau in the Volume Time Curve resulting in no change in volume for approximately 1 to 2 seconds (no change in volume means that volume stays within $\pm$ 40 cm^3).

OR

2. A forced exhalation of reasonable duration (between 3 and 15 seconds).

OR

3. The participant cannot, for legitimate reasons, continue further exhalation.

B. Determining a satisfactory start of test:

1. To achieve accurate 'time zero' (i.e. the starting point of the curve for measurement purposes) and to ensure that the FEV_1 comes from a maximal effort curve, the extrapolated volume should be less than 5% of the FVC or 100 cm^3, whichever is greater (see example of a late start with a tangent line drawn to determine time zero and extrapolated volume).

    a. Generally this means that if the curve starts with a straight vertical line, this line must be less than approx. ¼ inch.

    b. Cough during the first second of the test automatically invalidates the test (a cough of sputtering at the end of the test does not necessarily eliminate the test, if all other criteria are met).

C. Determining whether the curve is acceptable, given that the start and end of the test are acceptable:

1. The tester should observe that the participant understood the instructions and performed the maneuver with a maximum inspiration, with a good start, with a smooth continuous exhalation, with maximal effort, and <u>without</u> any of the following problems (see attached curves):

    a. coughing during the first second of the maneuver, or any other cough that, in the tester's judgement, interferes with measurement of accurate results.

    b. valsalva maneuver (glottis closure).

    c. early termination of expiration (as indicated by a sudden drop-off of the Flow Volume Curve)

    d. a leak

    e. an obstructed mouthpiece, e.g., obstruction due to the tongue being placed in front of the mouthpiece.

D. Acceptability Criteria - Overview

1. No hesitation at start of test
2. Rapid onset of flow
3. No evidence of leak
4. No cough or other evidence of stopping/starting of flow
5. Expiratory time (FET) of at least 3 seconds (possibly shorter for young children)
6. Technician assessment of participant test performance

V. Determining Reproducibility of the Tracings:

These criteria are used to decide whether the participant has provided two reproducible tracings. Please note that the *acceptability* criteria should be applied **before** the *reproducibility* criteria are even considered.

NO SPRIOGRAM SHOULD BE REJECTED SOLELY ON THE BASIS OF ITS POOR REPRODUCIBILITY, PROVIDED THAT 3 ACCEPTABLE TRACINGS ARE OBTAINED.

A. Reproducibility criteria:

1. The largest FVC and the second largest FVC from the set of acceptable curves should not vary by more than 5% of the largest reading or 0.100 L, whichever is greater.

2. The largest FEV_1 and the second largest FEV_1 from the set of acceptable tracings should not vary by more than 5% of the largest reading or 0.100 L, whichever is greater.

REFERENCE

1. American Thoracic Society. Standardization of spirometry—1987 update. Am Rev Respir Dis 1987; 136:1285.

Appendix 2
L.A. Spirometry Training Instructions

SPIROMETRY

Below is a description of the procedures for obtaining spirometry from the participant. Spirometry is the timed measurement of a person's lung volume. This is measured as the person blows out after taking a deep breath. It measures how much air is in the lungs and how effectively and quickly the lungs can be emptied. The measurements include a number of summaries, such as forced vital capacity (FVC, the volume of air that can be forcibly expelled from the lungs) and peak expiratory flow (PEF, the maximal expiratory flow rate). In L.A.FANS-2, the goal is to collect three acceptable spirometry measurements from adults and children 5 years of age and older, using a portable hand-held spirometer. The accuracy of the spirometry measurement depends on the respondent using the proper technique and exerting maximum effort. The procedure requires understanding, coordination, and cooperation between the FI and the respondent. The directions for using the device are in a separate document.

A. General Precautions

1. Wash your hands before and after handing mouthpieces and interior surfaces of the spirometer.
2. If you have any open cuts or sores on your hands, you must wear gloves.
3. Always wash your hands between measuring different respondents.
4. Clean equipment by wiping with alcohol swabs after each use.

B. Equipment

L.A.FANS-2 will use hand-held, portable electronic spirometers made by EasyOne. The specific model is the EasyOne Diagnostic Spirometer. The components of the system include the following:

1. The hand-held electronic spirometer.
2. 2 AA batteries.
3. A supply of single-use, disposable Spirettes (the mouthpieces).
4. Disposable nose clips.
5. Alcohol swabs to wipe equipment.
6. Disposable non-latex gloves

The device will assess whether each measurement attempt is acceptable and will provide specific guidance, such as "blow harder" or "blow longer." The read-out window on the spirometer will provide suggestions to improve performance after each attempt.

C. Exclusions

Respondents excluded from spirometry include those who:

1. Have had any surgery on their chest or abdomen in the past three weeks.
2. Have been hospitalized for a heart problem (such as heart attack, angina or chest pain, congestive heart failure) in the past six weeks.
3. The presence of abdominal or chest pain (for any reason).
4. Oral or facial pain made worse by a mouthpiece.
5. Acute respiratory illness causing the respondent to cough, sneeze or suffer from bronchospasm.
6. Women in their 3rd trimester of pregnancy. (In general, pregnancy is not considered a medical exclusion criterion for spirometry testing. In fact, women with asthma or other respiratory conditions are often tested using spirometry throughout pregnancy in order to monitor their health. That said, for L.A. FANS-2 we will exclude women in their 3rd trimester. If any pregnant woman is anxious about the possibility that the test could be harmful to her pregnancy or fetus the field interviewer should excuse her from the test and still consider her eligible for the full health measures incentive).
7. If any respondent experiences dizziness during the procedure, testing should be stopped.

D. Information to Collect from Respondents

Questions in the laptop instruct you to ask respondents if they:

1. Have smoked cigarettes in the past one hour?
2. Have eaten a heavy meal in the past one hour?
3. Have used any medications to help them breathe (such as bronchodilators) in the past one hour?
4. Had a cough, cold, or other acute illness in the past week?
5. Had any respiratory infection (such as the flu, pneumonia, bronchitis, or a severe cold) in the past three weeks?
6. Are currently being treated for tuberculosis?

E. Preparing the Respondent

1. Explain that you will use your mouthpiece to demonstrate the entire procedure. Be careful to not blow into the respondent's face. Use the script in the box below to emphasize each of the following concepts:
    a. Proper placement of the mouthpiece.
    b. Proper placement of noseclip on the nose.
    c. Blasting air into the mouthpiece.
    d. Maximal inhalation. (deepest breath)

    Remember: When you demonstrate the maneuver yourself, using a mouthpiece held in your hand, demonstrate with **maximum** effort so they will use maximum effort!

2. Prepare the respondent to do an exhalation, using the following instructions as a script. Tell them that these are the steps you are going to want them to do:

   a. Stand up straight, feet flat on the floor, do not lean forward
   b. Once I hand you the spirometer, take in as MUCH air as you POSSIBLY can, until your lungs are COMPLETELY full.
   c. Quickly make a tight seal on the mouthpiece with your lips, teeth resting in the grooves. Do NOT bite down and try to keep your tongue out of the way.
   d. Then, BLAST the air out as HARD and as FAST as you POSSIBLY can and keep blowing until I tell you to stop, even though it may seem like you are out of air. Do not bend forward at your waist as you blow out. It's OK if you bend your knees and crouch down a bit.

F. Coaching the Respondent

Your ability to successfully coach the respondent at the start of the test will lead to the best results. Don't worry about looking silly!

1. Open a mouthpiece for the respondent and, without connecting it to the spirometer, let the respondent practice putting it in his or her mouth and getting a good seal.

2. Ask the respondent to stand up and loosen any tight clothing.

3. Just in case the participant gets dizzy, place a non-rolling chair behind the participant. Or the respondent can stand with a firm surface, such as a wall, behind him or her.

4. Insert the respondent's mouthpiece into the spirometer and begin the first effort. See "Instructions for Using the EasyOne Device" for additional details on the operation of the device.

5. Use the feedback from the spirometer to judge whether the respondent is blowing out correctly. You may need to give additional instructions to the respondent. You need to use your judgment about what to say after watching how the respondent performs the test and after reading what the spirometer says. If the respondent stops early say, "Even if your lungs feel empty, small amounts of air are still coming out, so keep pushing and blowing." Another example might be "it's okay to bend your knees but make sure you don't lean forward."

6. Continue by having the respondent perform a spirometry tests until three acceptable efforts have been obtained. If, after **8** tries, the person has not completed three acceptable sessions, discontinue the test.

7. Once the respondent fully understands how to do the test correctly, very similar measurements should be obtained when the test is repeated. This means that the respondent should be able to blow out most of the air from his or her lungs in the first second of the effort.

8. Here is a list of the different prompts that will follow each test on the display of the EasyOne device. Be prepared to know how to follow up each prompt with proper coaching:

Prompt	Coaching response
Don't hesitate	The respondent should exhale in one breath and should not stop in-between.
Blast out faster	The respondent must exhale more explosively and as firmly and quickly as possible.
Blow out longer	The respondent has discontinued exhalation too early. The patient must exhale even more and press as much air as possible out of his/her lungs.
Wait until buzz before blowing out	The respondent has started to blow out before the device is ready for the test.
Good effort, do next	Good test. Just one to two more good tests and the test is complete.
Blast out harder	The test differs greatly from the previous tests. The patient can blow still more firmly and achieve a higher peak flow.
Deeper breath	The test differs greatly from previous tests. The patient can inhale even more deeply and exhale even more air.
Session complete	The test is complete. An adequate number of good tests have been conducted.

9. Here are additional instructions you may need to include in your coaching:
   a. If the respondent starts to exhale too quickly: "Fill your lungs fully, then stop a moment, bring the mouthpiece up to your mouth and breathe out as fast as you can."
   b. "Keep the mouthpiece away from your mouth while you are breathing in."
   c. "Put the mouthpiece between your teeth and seal your mouth around the tube, not allowing any air to leak out the sides."
   d. If the respondent makes a lot of noises in his or her throat: "Blow out as if you are saying the word 'haaa'."
   e. If the respondent gives up too quickly: "Try to keep going until I tell you to stop, even though it may feel like you are out of air."
   f. For **children** with short attention spans try engaging the child in a game. For example, if they are having a hard time blowing hard enough at the start of the test, put a piece of paper on a table and challenge them to blow it off with one blast of air. If they are having trouble blowing long enough, tell them to imagine they are blowing candles out at their next birthday, and they have to keep blowing to get them all out in one breath. Although you may need to loudly encourage

them to complete the effort, be careful about yelling at the children, as this may scare them.

G. Common Errors

1. Not taking a deep enough breath
2. Leaking air around mouthpiece
3. Slow start to blow out
4. Poor effort in blowing out
5. Stop exhaling too soon
6. Poor posture, especially leaning forward
7. Respondent puts tongue in the mouthpiece (tell him/her not to)
8. Respondent has extra physical efforts such as coughing, vocalizing, or puffing cheeks
9. The respondent flexs his/her neck
10. The respondent pauses just before blowing out
11. The respondent makes noises in his throat while blowing
12. Too much enthusiasm during the blow on the part of the coach (you) may have a negative effect. Be aware of the affect you are having on the child or adult.

H. Reporting Results

We do not send spirometry results back to the respondents. One reason is because there is not a simple or easy way to summarize or interpret the spirometry results. If the participant asks for results, please explain that their results have to be put through a computer program to figure out what they mean. You can also say that you are not qualified to interpret results.

Appendix 3
L.A. Spirometry Training Instructions - EasyOne

INSTRUCTIONS FOR USING THE EASYONE DEVICE

1. Turn the device on by pressing and holding the ON/OFF button until you hear a beep.

2. The Main menu appears (you will see “MAIN” along the left side of the screen). Select “Perform Test” by pressing the ENTER button.

3. In the next screen you will start a new test. The “NEW” option is already highlighted, so select this option by pressing ENTER.

NOTE: If at any point you need to go back to a previous screen or field, press and hold 0 Esc. You can scroll between different option within a screen be pressing the ◄ and ► buttons.
If device turns off, choose PERFORM TEST, then
RECALL and LAST TEST

4. In the next screen you will enter patient data:

   a. **ID** – you will have to enter a combination of numbers and letters. For example, if you need to enter a “2” followed by an “H”, you will have to press 2 on the keypad 4 times (in order to scroll past A, B, and C) and then press 4 2 times. If you make a mistake, use the ◄ key to scroll back. Once you are finished entering the ID, press ENTER.
   b. **Name** - enter the respondent’s initials
   c. **Birth** - enter the respondent’s date of birth
   d. **Height** -Enter “150”
   e. **Weight** - accept the default value, which is 0, by pressing ENTER
   f. **Ethnicity** - accept the default value, which is Caucasian
   g. **Gender** - accept the default value, which is male
   h. **Smoker** - accept the default value, which is no

i. **Asthma** - accept the default value, which is no
j. **Tech ID** - enter your FI ID #

5. Once you have entered all of the patient data, the Test menu appears (you will see "TEST" along the left side of the screen). Select the first test titled "FVC (Expiratory)" by pressing ENTER.

6. Insert the spirette into the device: open the plastic wrap at the end with the smaller opening and insert it through the hole at the top of the device. Line up the arrows on the front of the device and then push it down until it stops. Then remove the plastic wrap from around the top of the mouthpiece (this is so you don't have to touch the mouthpiece with your hands).

7. The next screen will instruct you to block the spirette. Place your palm over the bottom of the spirette and press ENTER.

8. Keep the spirette blocked until you see "Blast Out" on the screen. Quickly hand the device to the respondent and instruct them on completing the maneuver [see "Step by Step Verbal Instructions for Spirometry"].

9. Once you hear the end-of-test beep, the maneuver is complete and you will see the results on the screen. Press ENTER to advance to the "Session Quality" screen. If the test was acceptable, you will be instructed to move on to the next effort. If the test was unacceptable, you will be instructed on how to coach the respondent and they will have to retry the effort [see "Coaching" section in main Spirometry handout].

10. Once 3 acceptable efforts have been recorded, the session will be over and you can turn the device off by pressing and holding the ON/OFF button.

11. Have respondent pull spirette from device and dispose.

Appendix 4
L.A. Spirometry Training – Step by Step Verbal Instructions

STEP-BY-STEP VERBAL INSTRUCTIONS FOR SPIROMETRY

1. Stand up straight, feet flat on the floor, do not lean forward. Put on noseclips.

2. Once I hand you the spirometer, take in as **MUCH** air as you **POSSIBLY** can, until your lungs are **COMPLETELY** full.

3. Quickly make a tight seal on the mouthpiece with your lips, teeth resting in the grooves. Don't bite down and try to keep your tongue out of the way.

4. Then, **BLAST** the air out as **HARD** and as **FAST** as you **POSSIBLY** can. Keep blowing until I tell you to stop, even though it may seem like you are out of air. Do not bend forward at your waist as you blow out.

Appendix 5
L.A. Spirometry Training – Example Curves

EasyOne(TM) DIAGNOSTIC 2.9
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SN 54822

Patient Information

Name	LC
ID	9999
Age	26 (10/10/1979)
Height	150 cm
Weight	
Gender	MALE
Ethnic	CAUCASIAN
Smoker	NO
Asthma	NO

Test Information

Test Date	08/10/06 12:46am
Post Time	--:--
Test Mode	DIAGNOSTIC
Interpretation	NLHEP
Predicted Ref	Nhanes III
Value Select	BEST VALUE
Tech ID	
Automated QC	ON
BTPS (IN/EX)	-.--/ 1.04

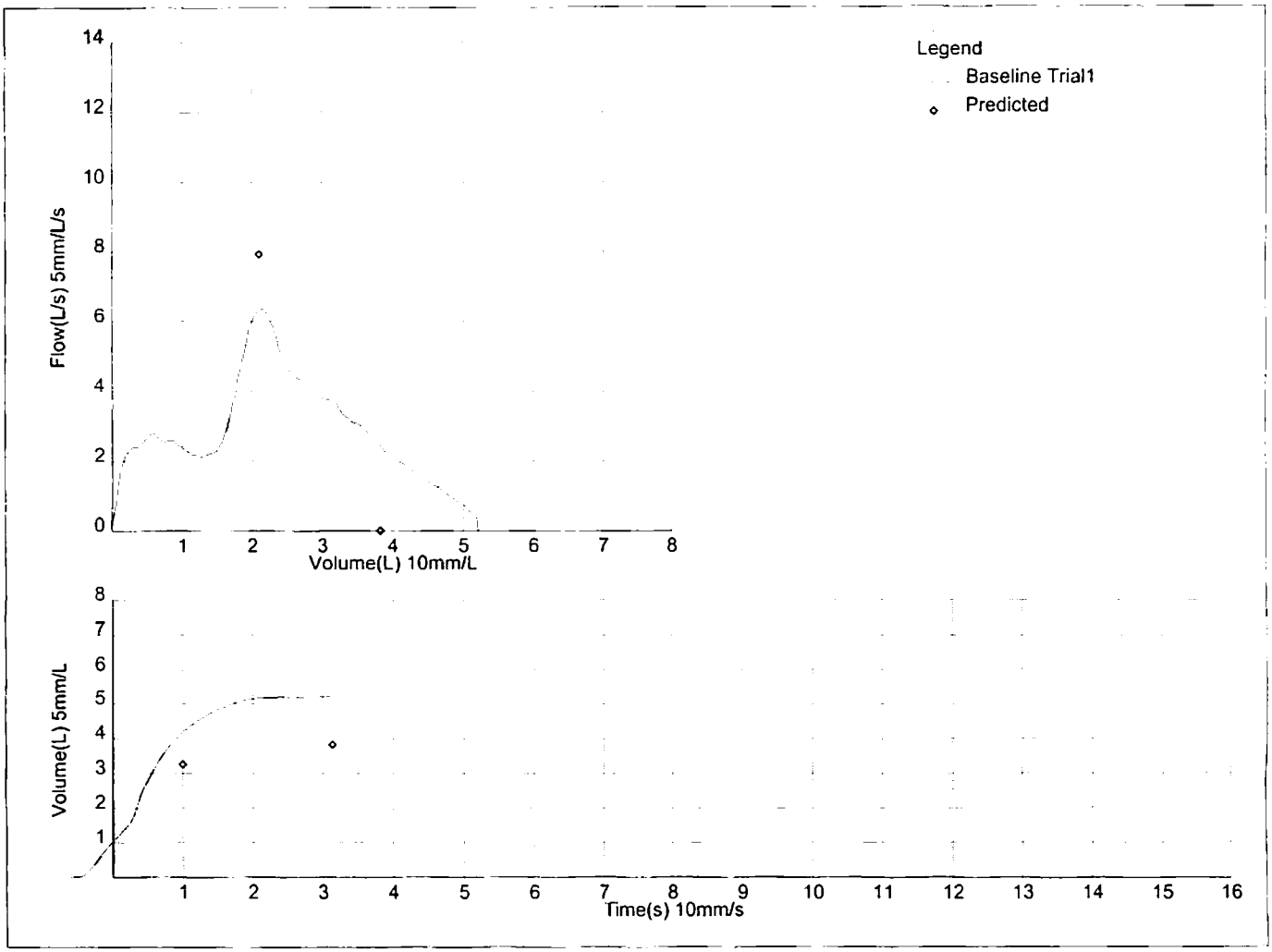
Test Results

Your FEV1 is 129% Predicted

Parameter	Baseline Best	Trial1#	Pred	%Pred
FVC(L)	5.21	5.21	3.84	136
FEV1(L)	4.21	4.21	3.27	129
FEV1/FVC	0.81	0.81	0.83	98
PEF(L/min)	379	379	476	79
FEF25-75(L/s)	3.57	3.57	3.73	96
FET(s)	3.14	3.14	-.--	--

Baseline FEV1 Var= -.-- L; FVC Var= -.-- L; Session Quality F
Interpretation No interpretation, no acceptable maneuvers
Caution: No Acceptable Maneuvers - Interpret With Care.

DON'T HESITATE



EasyOne(TM) DIAGNOSTIC 2.9
(c)ndd 2000-2004
EasyWare 2. 7. 1. 0
SN 54822

Patient Information

Name	LC
ID	99
Age	26 (10/10/1979)
Height	150 cm
Weight	
Gender	MALE
Ethnic	CAUCASIAN
Smoker	NO
Asthma	NO

Test Information

Test Date	08/10/06 01:04am
Post Time	--:--
Test Mode	DIAGNOSTIC
Interpretation	NLHEP
Predicted Ref	Nhanes III
Value Select	BEST VALUE
Tech ID	
Automated QC	ON
BTPS (IN/EX)	-.--/ 1.04

Test Results

Your FEV1 is 102% Predicted

Parameter	Baseline Best	Trial1#	Pred	%Pred
FVC(L)	5.07	5.07	3.84	132
FEV1(L)	3.33	3.33	3.27	102
FEV1/FVC	0.66*	0.66*	0.83	80
PEF(L/min)	270*	270*	476	57
FEF25-75(L/s)	2.54*	2.54*	3.73	68
FET(s)	5.38	5.38	-.--	--

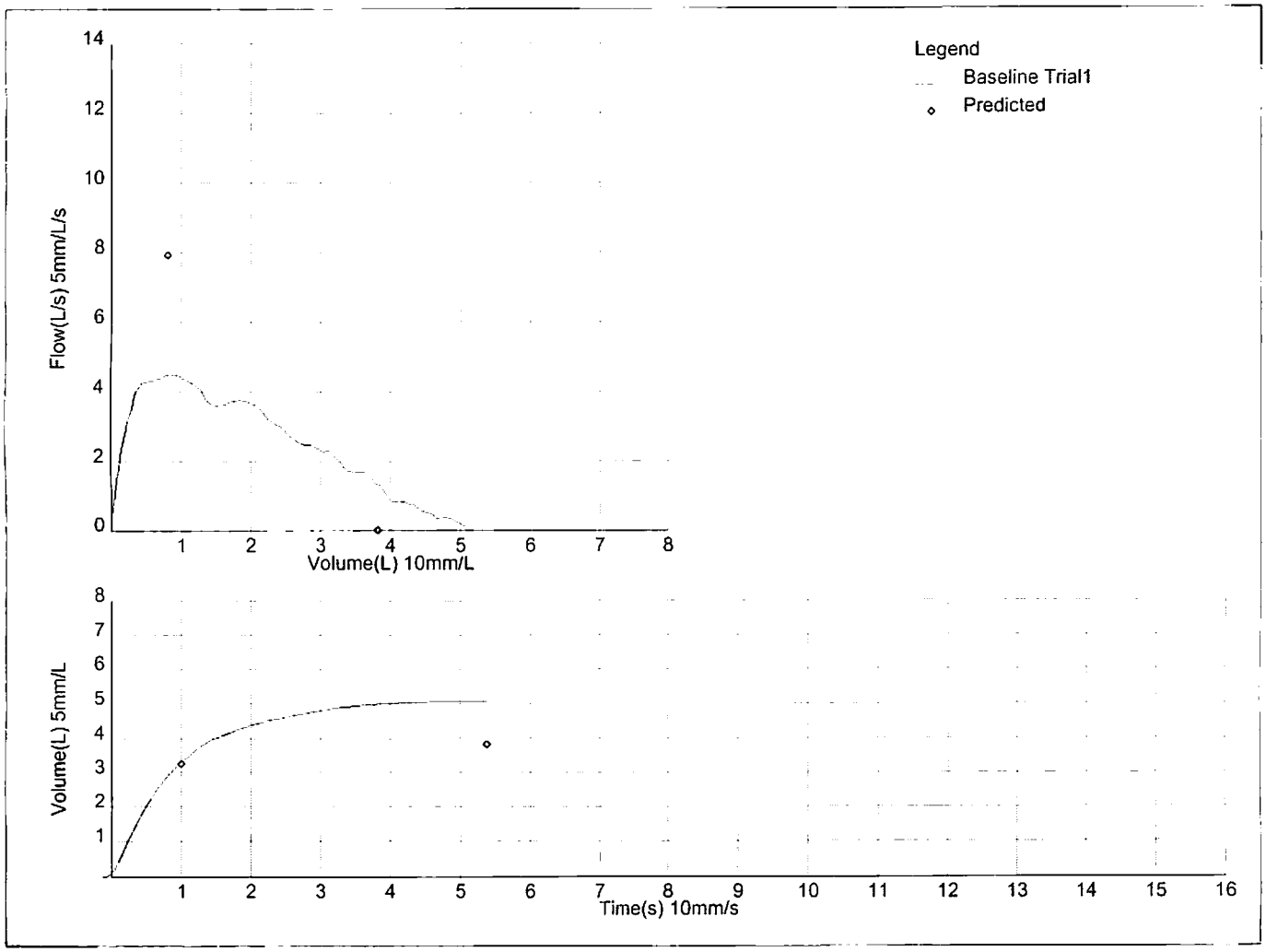
* Indicates Below LLN or Significant Post Change

Baseline FEV1 Var= -.-- L; FVC Var= -.-- L; Session Quality F

Interpretation No interpretation, no acceptable maneuvers

Caution: No Acceptable Maneuvers - Interpret With Care.

BLAST OUT FASTER



EasyOne(TM) DIAGNOSTIC 2.9
(c)ndd 2000-2004
EasyWare 2. 7. 1. 0
SN 54822

Patient Information

Name	LC
ID	9999
Age	26 (10/10/1979)
Height	150 cm
Weight	
Gender	MALE
Ethnic	CAUCASIAN
Smoker	NO
Asthma	NO

Test Information

Test Date	08/10/06 12:49am
Post Time	--:--
Test Mode	DIAGNOSTIC
Interpretation	NLHEP
Predicted Ref	Nhanes III
Value Select	BEST VALUE
Tech ID	
Automated QC	ON
BTPS (IN/EX)	-.--/ 1.04

Test Results

Your FEV1 is 72% Predicted

Parameter	Baseline Best	Trial1	Trial2#	Pred	%Pred
FVC(L)	2.36*	2.36*	1.99*	3.84	61
FEV1(L)	2.35*	2.35*	1.99*	3.27	72
FEV1/FVC	1.00	1.00	1.00	0.83	121
PEF(L/min)	522	522	472	476	110
FEF25-75(L/s)	6.20	6.20	6.21	3.73	166
FET(s)	2.53	2.53	0.34	-.--	--

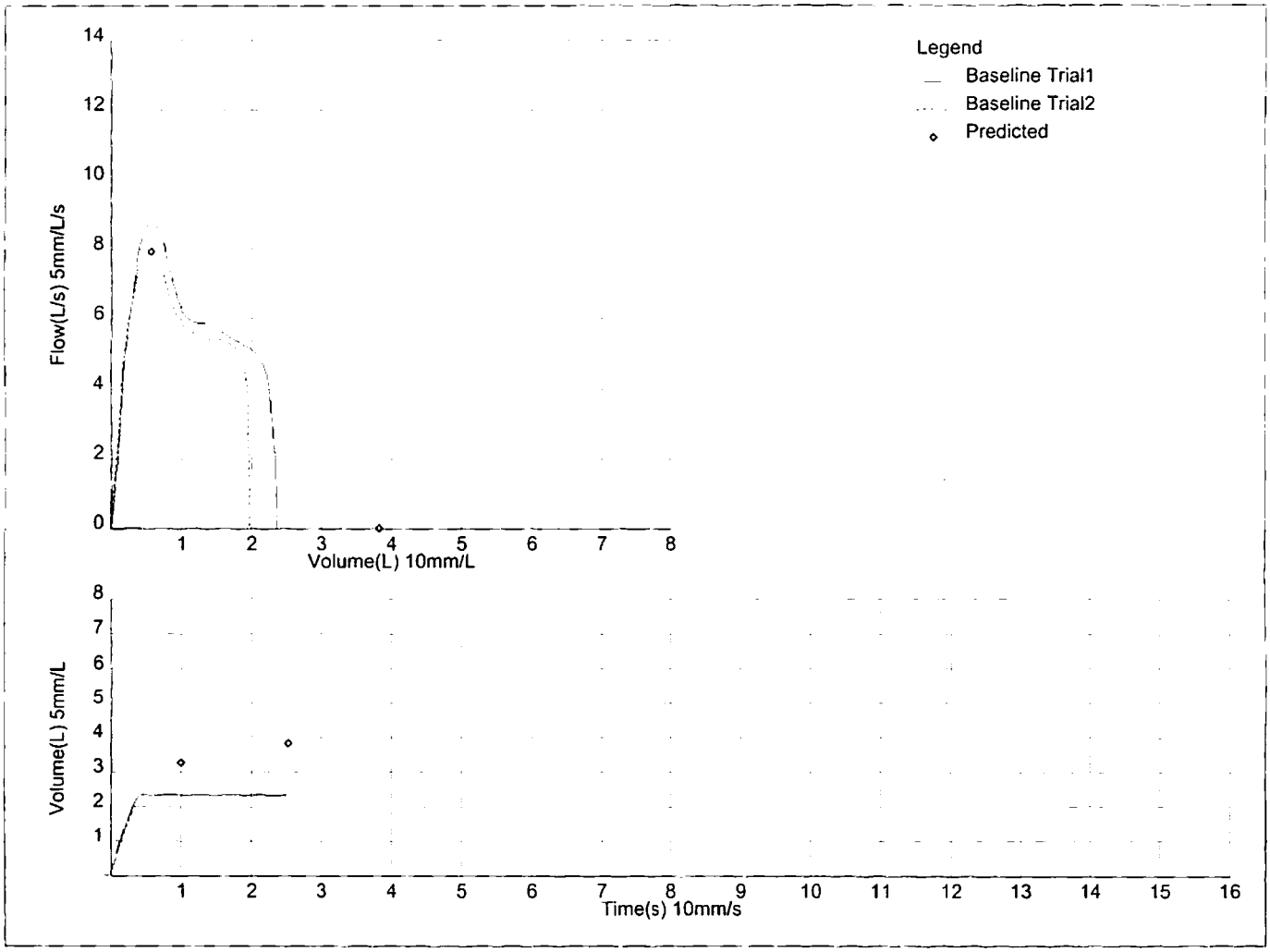
* Indicates Below LLN or Significant Post Change

Baseline FEV1 Var=0.36L 15.4%; FVC Var=0.37L 15.6%; Session Quality D

Interpretation Low vital Capacity possibly due to restriction of lung volumes

Caution: Only One Acceptable Maneuver - Interpret With Care.

BLOW OUT LONGER



EasyOne(TM) DIAGNOSTIC 2.9
(c)ndd 2000-2004
EasyWare 2. 7. 1. 0
SN 54822

Patient Information

Name	LC
ID	99
Age	26 (10/10/1979)
Height	150 cm
Weight	
Gender	MALE
Ethnic	CAUCASIAN
Smoker	NO
Asthma	NO

Test Information

Test Date	08/10/06 12:50am
Post Time	--:--
Test Mode	DIAGNOSTIC
Interpretation	NLHEP
Predicted Ref	Nhanes III
Value Select	BEST VALUE
Tech ID	
Automated QC	ON
BTPS (IN/EX)	-.--/ 1.04

Test Results

Your FEV1 is 120% Predicted

Parameter	Baseline Best	Trial1	Trial2#	Pred	%Pred
FVC(L)	4.90	4.90	3.15*	3.84	128
FEV1(L)	3.93	3.93	2.68*	3.27	120
FEV1/FVC	0.80	0.80	0.85	0.83	97
PEF(L/min)	498	498	266*	476	104
FEF25-75(L/s)	3.61	3.61	2.59*	3.73	97
FET(s)	3.85	3.85	3.64	-.--	--

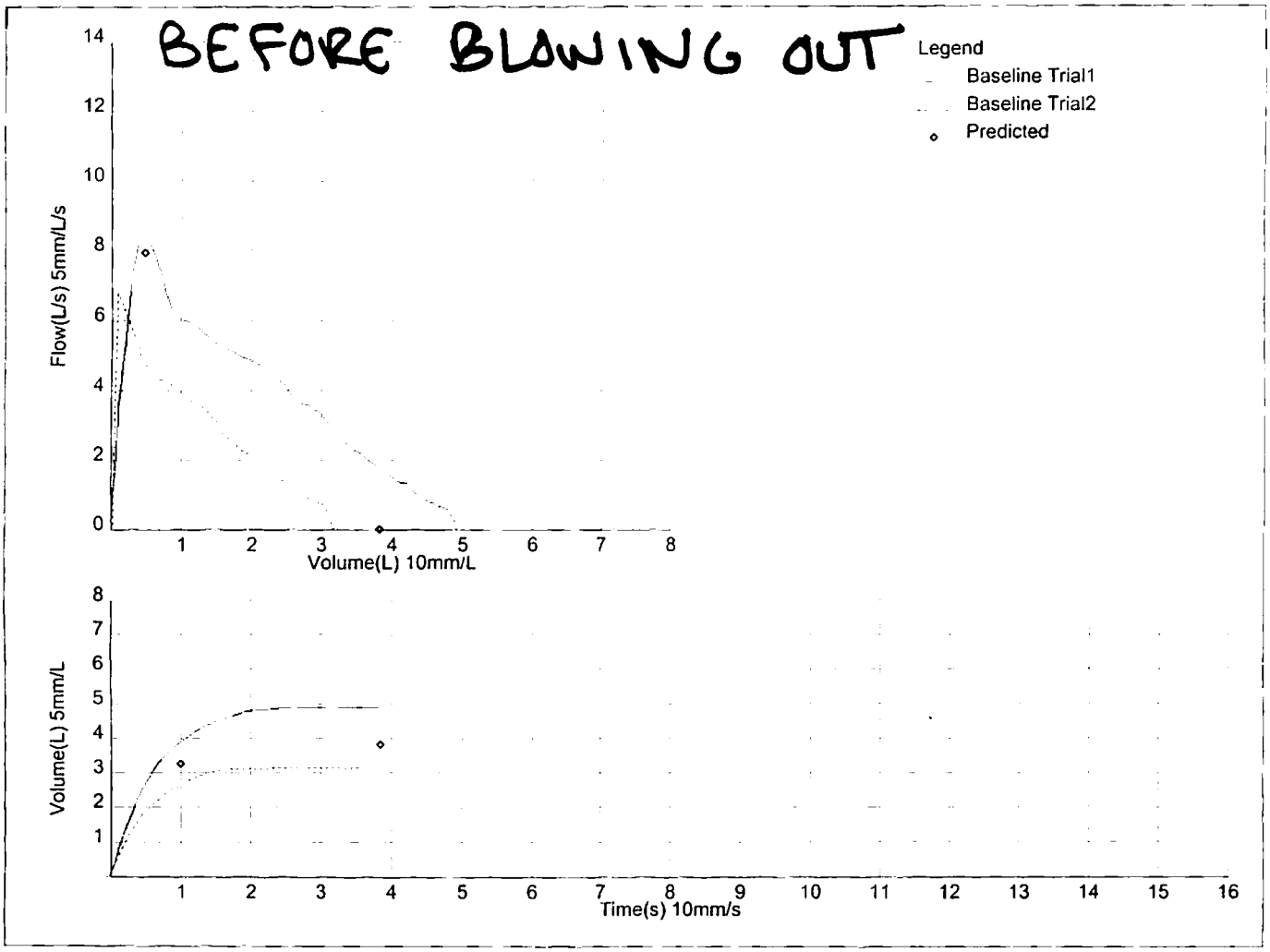
* Indicates Below LLN or Significant Post Change

Baseline FEV1 Var=1.25L 31.8%; FVC Var=1.75L 35.7%; Session Quality D

Interpretation Normal Spirometry

Caution: Only One Acceptable Maneuver - Interpret With Care.

WAIT UNTIL BUZZ BEFORE BLOWING OUT



EasyOne(TM) DIAGNOSTIC 2.9
(c)ndd 2000-2004
EasyWare 2. 7. 1. 0
SN 54822

Patient Information

Name	LC
ID	99
Age	26 (10/10/1979)
Height	150 cm
Weight	
Gender	MALE
Ethnic	CAUCASIAN
Smoker	NO
Asthma	NO

Test Information

Test Date	08/10/06 12:52am
Post Time	--:--
Test Mode	DIAGNOSTIC
Interpretation	NLHEP
Predicted Ref	Nhanes III
Value Select	BEST VALUE
Tech ID	
Automated QC	ON
BTPS (IN/EX)	-.--/ 1.04

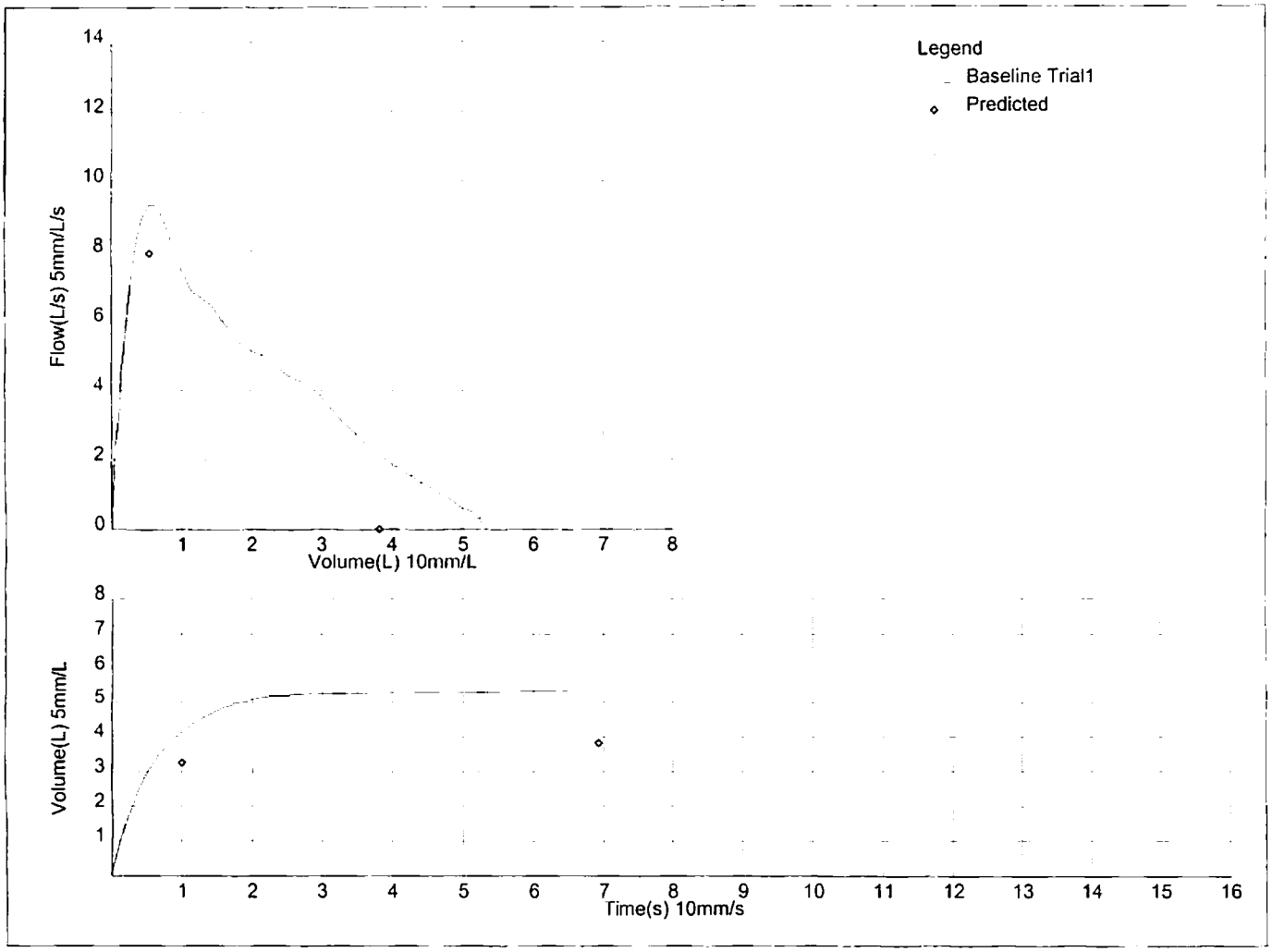
Test Results

Your FEV1 is 128% Predicted

Parameter	Baseline Best	Trial1	Pred	%Pred
FVC(L)	5.35	5.35	3.84	139
FEV1(L)	4.18	4.18	3.27	128
FEV1/FVC	0.78	0.78	0.83	95
PEF(L/min)	553	553	476	116
FEF25-75(L/s)	3.61	3.61	3.73	97
FET(s)	6.93	6.93	-.--	--

Baseline FEV1 Var= -.-- L; FVC Var= -.-- L; Session Quality D
Interpretation Normal Spirometry
Caution: Only One Acceptable Maneuver - Interpret With Care.

GOOD EFFORT, DO NEXT



EasyOne(TM) DIAGNOSTIC 2.9
(c)ndd 2000-2004
EasyWare 2. 7. 1. 0
SN 54822

Patient Information

Name	LC
ID	99
Age	26 (10/10/1979)
Height	150 cm
Weight	
Gender	MALE
Ethnic	CAUCASIAN
Smoker	NO
Asthma	NO

Test Information

Test Date	08/10/06 12:54am
Post Time	--:--
Test Mode	DIAGNOSTIC
Interpretation	NLHEP
Predicted Ref	Nhanes III
Value Select	BEST VALUE
Tech ID	
Automated QC	ON
BTPS (IN/EX)	-.--/ 1.04

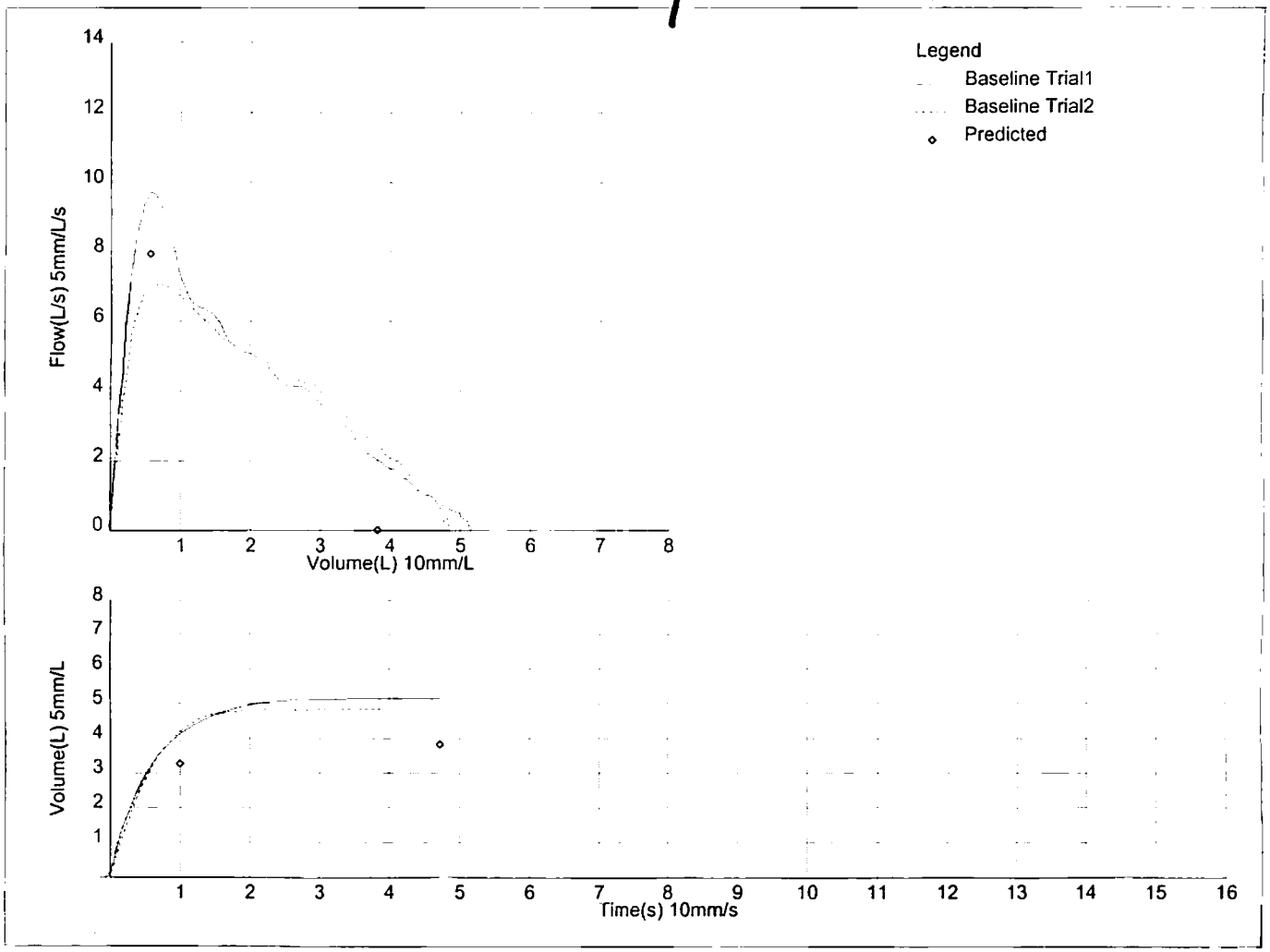
Test Results

Your FEV1 is 129% Predicted

Parameter	Baseline Best	Trial1	Trial2	Pred	%Pred
FVC(L)	5.15	5.15	4.85	3.84	134
FEV1(L)	4.21	4.14	4.21	3.27	129
FEV1/FVC	0.82	0.80	0.87	0.83	99
PEF(L/min)	575	575	423	476	121
FEF25-75(L/s)	3.73	3.73	4.41	3.73	100
FET(s)	4.72	4.72	3.95	-.--	--

Baseline FEV1 Var=0.08L 1.8%; FVC Var=0.29L 5.7%; Session Quality D
Interpretation Normal Spirometry
Caution: Maneuvers Not Reproducible - Interpret With Care.

BLAST OUT HARDER / DEEPER BREATH



EasyOne(TM) DIAGNOSTIC 2.9
(c)ndd 2000-2004
EasyWare 2. 7. 1. 0
SN 54822

Patient Information

Name	LC
ID	99
Age	26 (10/10/1979)
Height	150 cm
Weight	
Gender	MALE
Ethnic	CAUCASIAN
Smoker	NO
Asthma	NO

Test Information

Test Date	08/10/06 12:54am
Post Time	--:--
Test Mode	DIAGNOSTIC
Interpretation	NLHEP
Predicted Ref	Nhanes III
Value Select	BEST VALUE
Tech ID	
Automated QC	ON
BTPS (IN/EX)	-.--/ 1.04

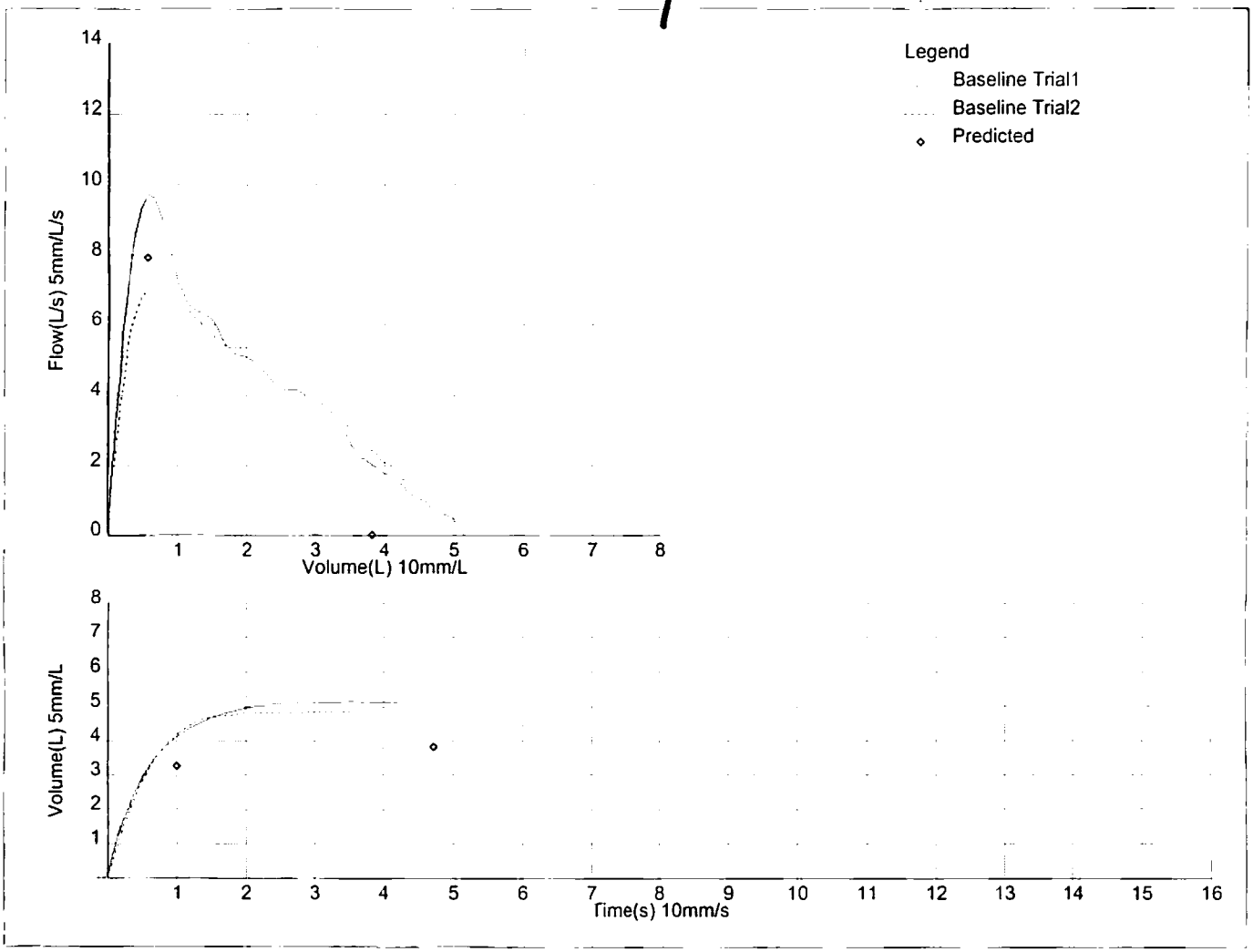
Test Results

Your FEV1 is 129% Predicted

Parameter	Baseline Best	Trial1	Trial2	Pred	%Pred
FVC(L)	5.15	5.15	4.85	3.84	134
FEV1(L)	4.21	4.14	4.21	3.27	129
FEV1/FVC	0.82	0.80	0.87	0.83	99
PEF(L/min)	575	575	423	476	121
FEF25-75(L/s)	3.73	3.73	4.41	3.73	100
FET(s)	4.72	4.72	3.95	-.--	--

Baseline FEV1 Var=0.08L 1.8%; FVC Var=0.29L 5.7%; Session Quality D
Interpretation Normal Spirometry
Caution: Maneuvers Not Reproducible - Interpret With Care.

BLAST OUT HARDER / DEEPER BREATH



Appendix D
L.A. FANS-2 Spirometry Protocol

1. Spirometry

Introduction: Spirometry is the timed measurement of a person's lung volume, assessed as the person blows out after taking a deep breath. It measures how much air is in the lungs and how effectively and quickly the lungs can be emptied. The measurements include a number of indices, such as forced vital capacity (the volume of air that can be forcibly expelled from the lungs) and peak expiratory flow (the maximal expiratory flow rate).

Protocol: In L.A.FANS-2, you will collect three acceptable/reproducible spirometry measurements from adults and children 5 years of age and older using a portable hand-held spirometer.

Procedure: The accuracy of the spirometry measurement depends on the respondent using the proper technique and exerting maximum effort. The procedure requires understanding, coordination, and cooperation between the FI and the respondent.

The following procedure describes how to perform spirometry on all subjects. This information is adapted from several sources, including the American Thoracic Society "Standardization of Spirometry, 1994 Update," *American Journal of Respiratory and Critical Care Medicine* 1995 (52): 1107-1136.

A. General Precautions

1. Wash your hands before and after handing mouthpieces and interior surfaces of the spirometer.
2. If you have any open cuts or sores on his/her hands, you must wear gloves.
3. Always wash your hands between measuring different respondents.
4. Clean equipment by wiping with alcohol swabs after each use.

B. Equipment

L.A.FANS-2 will use hand-held, portable electronic spirometers made by EasyOne. The specific model is the EasyOne Diagnostic Spirometer. The components of the system include the following:

1. The hand-held electronic spirometer.
2. 2 AA batteries.
3. A supply of single-use, disposable Spirettes (the mouthpieces).
4. Disposable nose clips.
5. Alcohol swabs to wipe equipment.
6. Disposable non-latex gloves

The read-out window on the spirometer will provide suggestions to improve performance after each attempt. It will assess whether each measurement attempt is acceptable and will provide specific guidance, such as "blow harder" or "blow longer."

See the EasyOne instructions for further details about the equipment.

C. Exclusions

Respondents excluded from spirometry include those who:

1. Have had any surgery on their chest or abdomen in the past three weeks.
2. Have been hospitalized for a heart problem (such as heart attack, angina or chest pain, congestive heart failure) in the past six weeks.
3. The presence of abdominal or chest pain (for any reason).
4. Oral or facial pain made worse by a mouthpiece.
5. Acute respiratory illness causing the respondent to cough, sneeze or suffer from bronchospasm.
6. Women in their 3rd trimester of pregnancy*
7. If any respondent experiences dizziness during the procedure, testing should be stopped.

*A word about women who are pregnant:

In general, pregnancy is not considered a medical exclusion criterion for spirometry testing. In fact, women with asthma or other respiratory conditions are often tested using spirometry throughout pregnancy in order to monitor their health. That said, for LAFANS we will exclude women in their 3rd trimester and if any pregnant woman is anxious about the possibility that the test could be harmful to her pregnancy or fetus the field interviewer should simply excuse her from the test and still consider her eligible for the full health measures incentive.

D. Information to Collect from Respondents

Questions in the laptop instruct you to ask respondents if they:

1. Have smoked cigarettes in the past one hour.
2. Have eaten a heavy meal in the past one hour.

3. Have used any medications to help them breathe (such as bronchodilators) in the past one hour.
4. Had a cough, cold, or other acute illness in the past week.
5. Had any respiratory infection (such as the flu, pneumonia, bronchitis, or a severe cold) in the past three weeks.
6. Are currently being treated for tuberculosis.

E. Configuring the Easy One Spirometer

Each day that you use the spirometer, begin by checking its configuration. Follow these steps:

1. For the date of the tests: Choose "Configuration" from the main menu, then choose "General Settings," and check and update the field entitled "Date."
2. To be able to enter your FI ID number: Choose "Configuration" from the main menu, then choose "General Settings," and set the Tech ID field to "yes."
3. To make sure three readings are recorded and stored: Choose "Configuration" from the main menu, then choose "Test Settings," and set the Storage field to "3 Best."
4. To make sure three readings are reported: Choose "Configuration" from the main menu, then choose "Report Settings," and set the Curve field to "3 Best."
5. To set the height to centimeters: Choose "Configuration" from the main menu, then choose "General Settings," and set the Height Unit field to "m/cm."

E. Preparing and Using the Easy One Spirometer

1. For each respondent, you must enter information into the spirometer on the "Patient Data" screen. Do the following:

    a. ID—enter the respondent's L.A. FANS-2 ID #
    b. Name—enter the respondent's initials
    c. Birth—enter the respondent's date of birth
    d. Height—enter the respondent's height in centimeters, based on the measurement you recorded earlier; if the respondent declined to have his or her height measured or you were unable to measure the respondent's height, enter "150"
    e. Weight—accept the default value, which is 0
    f. Ethnicity—accept the default value, which is Caucasian
    g. Gender—accept the default value, which is male
    h. Smoker—accept the default value, which is no
    i. Asthma—accept the default value, which is no
    j. Tech ID—enter your FI ID #

2. You can let the respondent try a maximum of eight attempts to get three satisfactory tests.
3. The respondent has performed an acceptable test when the reading in the spirometer's window says "good effort, do next."

4. The respondent has performed three acceptable tests when the reading in the spirometer's window says "session complete."
5. Results are stored on the spirometer, which will be able to hold results for about 200 respondents. You will be told how to bring or ship your spirometer to RTI so the results can be downloaded at a later time.
6. If three "acceptable" tests are not obtained, explain why in the comments field in the laptop
7. Note any deviation from the protocol or any problems encountered in the comments section in the laptop.

F. Preparing the Respondent

1. Explain and demonstrate the entire procedure to the respondent (using your own mouthpiece) before the respondent attempts the process. Be careful to not blow into the respondent's face. Explain and demonstrate the following steps:
    a. Proper placement of the mouthpiece.
    b. Proper placement of noseclip on the nose.
    c. Maximal inhalation.
    d. Blasting air into the mouthpiece.
2. Open a mouthpiece for the respondent and, without connecting it to the spirometer, let the respondent practice putting it in his or her mouth and getting a good seal.
3. Ask the respondent to stand up and loosen any tight clothing.
4. Place a non-rolling chair behind the participant. As an alternative, the respondent can stand with a firm surface, such as a wall, behind him or her.
5. Insert the respondent's mouthpiece into the spirometer.
6. Prepare the respondent to do an exhalation, using the following instructions as a script:
    a. First put this clip on your nose.
    b. Lift up your chin to help open your airway.
    c. Now I'm going to hand you the spirometer.
    d. Take a great big deep breath of air as far as you can inhale.
    e. Without pausing, put the mouthpiece in your mouth, between your teeth, and seal your lips tightly around it.
    f. Blast out the air as hard and fast as you can!
    g. Keep on blowing out the same breath of air until I tell you to stop.
7. After each attempt give the respondent feedback based on the message from the spirometer and your own observations. If the respondent stops early say, "Even if your lungs feel empty, small amounts of air are still coming out, so keep pushing and blowing." Another example might be "it's okay to bend your knees but make sure you don't lean forward."

G. Common Errors

1. Not taking a deep enough breath
2. Leaking air around mouthpiece
3. Slow start to blow out

4. Poor effort in blowing out
5. Stop exhaling too soon
6. Poor posture, especially leaning forward
7. Respondent puts tongue in the mouthpiece (tell him/her not to)
8. Respondent has extra physical efforts such as coughing, vocalizing, or puffing cheeks
9. The respondent is flexing his/her neck
10. The respondent pauses just before blowing out
11. The respondent makes noises in his throat while blowing
12. Too much enthusiasm during the blow on the part of the coach (you) may have a negative effect. Be aware of the affect you are having on the child or adult.

H. Coaching the Respondent

Your ability to successfully coach the respondent at the start of the test will lead to the best results. Begin by giving a simple but full explanation to the respondent of what the spirometry test involves, as follows:

1. **"Please stand (with the wall behind you) and whenever you are ready, take as deep a breath as you can until it feels like you cannot get any more air into your lungs. Place your mouth around the mouthpiece with your lips tightly sealed, and then breathe out as hard, as fast, and as long as you can. I want you to make the air "BLAST" out of your lungs. Keep breathing out until I tell you to stop."**
    a. Observe the respondent carefully while he or she is blowing out to make sure that he or she has fully understood the instructions and is performing the test correctly.
    b. Encourage the respondent to keep pushing air out of the lungs throughout the entire test. For example, tell the participant to "keep going, keep blowing…"

2. Continue by having the respondent perform a second spirometry test. Use the feedback from the spirometer to judge whether the respondent is blowing out correctly. You may need to give additional instructions to the respondent. You need to use your judgment about what to say after watching how the respondent performs the test and after reading what the spirometer says.

    Once the respondent fully understands how to do the test correctly, very similar measurements should be obtained when the test is repeated. This means that the respondent should be able to blow out most of the air from his or her lungs in the first second of the effort.

    Here are additional instructions you may need to include in your coaching:

    - If the respondent starts to exhale too quickly: "Fill your lungs fully, then stop a moment, bring the mouthpiece up to your mouth and breathe out as fast as you can."
    - "Keep the mouthpiece away from your mouth while you are breathing in."

- "Put the mouthpiece between your teeth and seal your mouth around the tube, not allowing any air to leak out the sides."
- If the respondent makes a lot of noises in his or her throat: "Blow out as if you are saying the word 'haaa'."
- If the respondent gives up too quickly: "Try to keep going until I tell you to stop, even though it may feel like you are out of air."

3. When you demonstrate the maneuver yourself, using a mouthpiece held in your hand, demonstrate with **maximum** effort so they will use maximum effort!

4. For children with short attention spans try engaging the child in a game. For example, if they are having a hard time blowing hard enough at the start of the test, put a piece of paper on a table and challenge them to blow it off with one blast of air. If they are having trouble blowing long enough, tell them to imagine they are blowing candles out at their next birthday, and they have to keep blowing to get them all out in one breath.

I. Reporting Results

We do not send spirometry results back to the respondents. One reason is because there is not a simple or easy way to summarize or interpret the spirometry results. Explain to the respondents that their results have to be put through a computer program to figure out what they mean. You can also say that you are not qualified to interpret results.